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(54) A sealing device and an insertion tool therefor.

(57) The sealing device is disclosed which is composed of an intra-arterial occluder (11) and an extra-arterial occluder (13), both preferably made of resilient biocompatible and/or bioabsorbable material and held in place via a toothed guide (12) extending integrally from the intra-arterial occluder (11). An insertion tool (23) may also be provided to effect sliding of the extra-arterial occluder (13) over the guide (12) and fixation of the extra-arterial occluder (13) to the guide in sealed relation over an opening in body tissue and safe cutting of the guide. A force gauge (47) is provided on the tool to indicate the sealing pressure on the intra-arterial occluder (11).

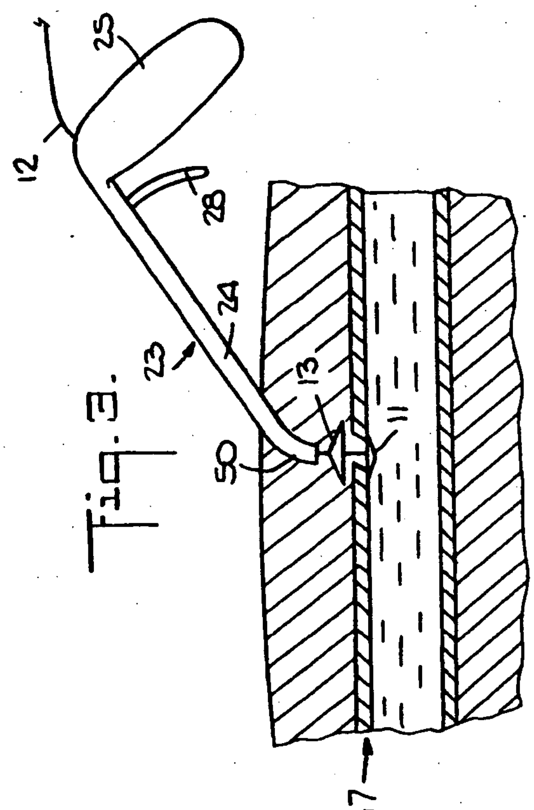

Fig. 3.

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This invention relates to a sealing device, for example a percutaneous arterial puncture sealing device, and an insertion tool therefor. More particularly, this invention relates to a sealing device for sealing an opening in a tissue and to a tool for implanting part of the device.

Heretofore, various interventional procedures have been performed which require formation of a puncture or the like in a tissue, for example in a vessel for the introduction of various devices, such as catheters. In this respect, access to arterial and venous vascular systems is necessary for both diagnostic and therapeutic medical procedures. For example, diagnostic arteriography is a radiological procedure which permits visualization of the arterial system for the diagnosis of disease in various organ systems. The most request applications are cardiac catheterization, peripheral vascular angiography, mesenteric angiography, and cerebral angiography. Therapeutic trans-arterial procedures, such as percutaneous transluminal coronary angioplasty (PTCA), have expanded the use of arterial access even further.

All these techniques involve cannulation of an artery so that a catheter may be inserted and advanced into the arterial system. Radio-opaque dye can be injected through the catheter and into the arterial system being examined while X-ray images are recorded. Alternatively, various transcatheter therapies can be employed in the artery, using balloon dilation devices, atherectomy devices, lasers, intra-aortic counterpulsation devices and left ventricular assist devices.

The femoral artery at the junction of the thigh and the abdomen is the most frequent arterial puncture site, but the carotid artery in the neck, the brachial artery in the midarm, and the axillary artery are also used. A percutaneous sheath is usually used whenever multiple catheters are used.

When the sheath is removed, the 1.5 to 5.0 millimetre hole in the artery would spurt blood with significant blood loss unless certain measures are taken. To allow sealing of the hole with a solid clot, heavy pressure is applied to the groin, either manually or with a large C shaped clamp for 10 to 30 minutes. Afterwards, the patient must lie flat on his/her back for 6 to 8 hours, and is usually kept in the hospital overnight for observation. Movement at the hip joint and any increase in intro-abdominal pressure, such as with coughing or bowel movement, can result in serious bleeding. There is a much greater tendency for serious bleeding to occur in patients given anticoagulants like aspirin and heparin or clot-dissolving drugs like streptokinase or tissue plasminogen activator.

Over one million diagnostic and therapeutic arteriographic procedures are done annually in the United States of America. The extra hospital days incurred purely to control bleeding from the arterial puncture site could be avoided if a safe, easy to use and effective arterial puncture sealant device were available. Such a device would allow same day discharge after angiographic procedures, with a savings of hundreds of millions of dollars. In addition to dollars saved, morbidity from bleeding and complications of blood transfusion could be significantly reduced or virtually eliminated.

Various suggestions have also been made, such as described in U.S. Patents 4,744,364; 4,852,568 and 4,890,612, for the mechanical sealing of such punctures. In such cases, a sealing device in the form of an expandable closure member is to be inserted through a puncture in the vessel, expanded while within the vessel and then retracted against and through the puncture by means of a retraction filament. Thereafter, the filament is left extending from the site of the puncture and through the skin of the patient while being secured in position on the skin of the patient as by a strip of conventional tape. However, such devices permit the exposed thread to be a site for infection. Further, anchorage of the enclosed member in pace by a thread which passes through the skin of a patient may not be reliable so that bleeding may occur by accidental displacement of the sealant device. Further, displacement of the sealant device into the artery would result in arterial occlusion and gangrene.

According to one aspect of the present invention, there is provided a sealing device comprising a first member for positioning on one side of a puncture in a tissue for closing over the puncture, and a guide means extending from the first member for passage through the puncture, the first member being circumferentially collapsible for passage through the puncture and resiliently expandable; characterized in that there is also provided a second member on the guide means for positioning on the opposite side of the puncture to seal the puncture, the second member being resiliently expandable from a circumferentially collapsible state.

Preferably the first member and the second member are made of at least one of a biocompatible material and a bioabsorbable material.

Preferably both the first member and the second member are made of bioabsorbable material and the first member has a faster rate of absorption than the second member.

Preferably at least one of the first and second member includes at least one of an anti-thrombotic material and a clot-promoting material therein.

The guide means is conveniently a guide wire. Preferably the guide wire has a portion containing a plurality of teeth inclined to tent to prevent the second member against movement in a direction away from the first member.

The second member may be of larger outer dimensions than the first member when in the expanded condition.

The present invention makes it possible reliably

to seal a puncture in a vessel or other tissue, in a simple manner.

The first biocompatible member may be a collapsible intro-arterial occluder, for positioning in a vessel to one side of an opening or puncture therein, and the second biocompatible member may be an extra-arterial occluder, which is movably mounted on the guide for positioning outside the vessel on an opposite side of the opening therein and in opposition to the first member in order to seal the opening.

The guide, which may be constructed in the form of a wire, should be made of biocompatible material, and can be integral with the intra-arterial occluder. Further, the guide may be provided with a plurality of teeth near the distal end region so that the extra arterial occluder can pass over the toothed portion in a direction towards the intra-arterial occluder while being retained against movement in the opposite direction.

The construction of the sealing device is such that each of the first and second members is circumferentially collapsible while being resiliently expandable.

The extra-arterial occluder is preferably constructed of larger outer dimensions than the intra-arterial occluder. Further, the intra-arterial and extra-arterial occluders can be made from biocompatible materials which have displayed their safety in humans, including but not limited to Dacron, nylon, Gortex or Teflon. The guide could be made from wire, but other synthetic materials such as a nylon would be applicable or even preferable.

Alternatively, and probably preferably, bioabsorbable materials for the occluders and guide may be ideal, because they would slowly dissolve and leave no residual foreign material behind. Bioabsorbable materials should be chosen so that the rate of absorption of the various parts is differential. Thus, the intra-arterial occluder and guide should be absorbed before the extra-arterial occluder to reduce the chance that the intra-arterial occluder could come free and embolize into the circulation.

Anti-thrombotic materials and/or drugs could be also used or incorporated into the blood contacting surface of the occluders. The occluders and guide may be radio-opaque so that they can be visualized fluoroscopically. Drugs or materials which promote coagulation could be used where the sealing surfaces exist.

The present invention also provides a tool for assisting in the insertion of the sealing device in a patient.

According to a second aspect of the present invention there is provided in combination a sealing device according to the first-mentioned aspect of the present invention and a seal insertion tool for use in placing the second member against the opposite side of the puncture, the seal insertion tool comprising:

a barrel;

a handle fixed to one end of the barrel;

a positioner member slidably mounted in the barrel; and

a trigger pivotally mounted with respect to the handle;

wherein the positioner member partially defines a chamber at one end of the barrel to receive the resiliently expandable second member which may serve as an extra-arterial occluder, and the trigger has one end disposed in the barrel; and

wherein there is means in the barrel between the one end region of the trigger and the positioner member for pushing the second member in a direction out of the barrel in response to pivoting of the trigger to expel the second member therefrom.

A preferred arrangement is that wherein the positioner member is hollow to define a bore for passage of an elongated guide means which is preferably a guide wire, extending from the first member which may serve as an intra-arterial occluder, through the extra-arterial occluder or other second member; and wherein there is a clamp within the handle for passage of the guide wire therethrough and for selectively clamping the guide wire in response to pivoting of the trigger prior to movement of the positioner member in the barrel.

Preferably there is also included a force gauge on the barrel for indicating a degree of pressure exerted via the clamped guide wire on the intra-arterial occluder or other first member at an end of the wire during movement of the positioner member relative thereto.

Preferably the tool includes a cutting means for severing the guide wire within the positioner member in response to retraction of the positioner member into the barrel.

Preferably the cutting means includes a pair of pincers in the positioner member disposed on opposite sides of the bore, a cam surface on the member and a cam on the barrel for slidably engaging the cam surface to radially deform the positioner member to effect closing of the pincers together to server the guide therebetween.

Preferably the positioner member has a flexible distal portion containing the pincers therein.

Basically, a preferred embodiment of the insertion tool has several functions. First, the tool is to deploy the extra-arterial occluder into the tissues outside the arterial wall. Second, the tool is to provide for an application of a calibrated pressure to the intra-arterial occluder at the contact point of the occluder with the lumen of the vessel. Third, the tool functions so as to cut the guide upon completion of the positioning of the intra-arterial and extra-arterial occluders.

In use, the tool is initially provided in a sterile condition with the extra-arterial occluder contained within the chamber at the distal end of the barrel of the

tool. At the conclusion of an arteriographic procedure, a percutaneous sheath would remain in the vessel, e.g. an artery. Thereafter, the intra-arterial occluder would be pushed through the sheath into the arterial lumen, for example, by an obturator whose length is only minimally greater than the sheath. In order to prevent arterial damage, the sheath is pulled back as the obturator is pushed in. As the intra-arterial occluder exits the sheath, the occluder expands due to the inherent natural resiliency, to normal full size. Once the occluder is in the artery, the position of the occluder can be confirmed by noting a free forward movement of the guide and resistance on pulling back. The sheath is then removed from the patient and the guide is pulled back until the intra-arterial occluder is snug against the luminal side of the arterial wall.

Thereafter, the tool is used to position the extra-arterial occluder. To this end, the guide is threaded through the extra-arterial occluder and tool. The tool is then manipulated to position the extra-arterial occluder outside the arterial wall, the appropriate position at which the extra-arterial occluder is to be deployed from the insertion tool into the patient can be determined by the location of the mark on the guide relative to the insertion tool. Alternatively, a stop can be placed on the guide which abuts the tool and prevents the tool tip from being inserted too close to the artery. At this position, the trigger on the tool is squeezed accomplishing several functions. First, the extra-arterial occluder is expelled from with the barrel. At this time, the extra-arterial occluder expands radially under the natural resiliency of the occluder. In this respect, the extra-arterial occluder may have a web-like perimeter from which struts project to positively engage the tissues as the extra-arterial occluder exits from the insertion tool, encouraging the extra-arterial occluder to open as intended.

Second, the two occluders are pressed together with a pressure regulated by the operator and measured by the tool. Further, since the distal end of the tool is flexible, the distal end is able to conform to a position substantially perpendicular to the artery as the occluders are pressed together.

By making the extra-arterial occluder larger than the intra-arterial occluder, several advantages are obtained. First, the larger size ensures that the extra-arterial occluder cannot accidently be inserted into the artery. Second, the force applied to hold the two occluders together will be applied to a larger surface area, thus reducing the pressure on the tissues. Thus, an excessively high pressure which could result in death of the underlying tissue (necrosis) is avoided.

Once the occluders are properly seated, the cutting means within the tool can be activated to sever the guide just after the point of exit from the extra-arterial occluder. The tool can then be withdrawn leaving the artery positively sealed. In this case, no part of the sealing device remains external to the patient. Instead, the entire sealing device is implanted within the tissue which heals around the device.

For a better understanding of the present invention and to show how the same may be carried into effect, reference will now be made, by way of example, to the accompanying drawings, in which:-

Fig. 1 illustrates a view at the conclusion of an arteriographic procedure with a sheath in place and an intra-arterial occluder, forming part of the device of the present invention, inserted within an arterial vessel;

Fig. 2 illustrates a view similar to Fig. 1 with the intra-arterial occluder of the sealing device in place against the wall of the vessel and with the sheath withdrawn;

Fig. 3 illustrates a view similar to that in Figs. 1 and 2 with an insertion tool in accordance with the present invention in place coaxially surrounding the guide extending from the intra-arterial occluder;

Fig. 4 illustrates a view similar to Fig. 3 of the tool at a time at which the extra-arterial occluder is being secured to the guide extending from the intra-arterial occluder;

Fig. 5 illustrates a cross-sectional view of an arterial vessel with a sealing device according to the present invention in place;

Fig. 6 illustrates on an enlarged scale a part cross-sectional view of the insertion tool shown in Fig. 3 as constructed in accordance with the present invention;

Fig. 7 illustrates a enlarged view of a sealing device in accordance with the present invention in the region of a puncture in an artery;

Fig. 8 illustrates a view of the sealing device of Fig. 7 in fixed position around an opening in a arterial vessel;

Fig. 9 illustrates a plan view of the intra-arterial occluder shown in Fig. 7; and

Fig. 10 illustrates a plan view of the extra-arterial occluder shown in Fig. 7.

Referring now to Fig. 7 and Fig. 8, the sealing device 10 is constructed of a biocompatible and/or bioabsorbable member in the form of an intra-arterial occluder 11, a guide means in the form of an elongated biocompatible and/or bioabsorbable wire 12 integral with the extending centrally from the intra-arterial occluder 11 and a second biocompatible and/or bioabsorbable member in the form of an extra-arterial occluder 13. As indicated, the guide 12 includes a portion extending from the intra-arterial occluder 11 which contains a plurality of saw teeth 14 while the extra-arterial occluder 13 is provided with an opening 15 (see Fig. 10) through which the guide 12 passes. The saw teeth 14 are wider in diameter than the opening 15 in the extra-arterial occluder 13 so that the ex-

tra-arterial occluder 13 can be passed over the teeth 14 in a direction towards the intra-arterial occluder 11. Thus, the extra-arterial occluder 13 can be advanced until a desired amount of pressure is placed on the tissues, such as the wall 16 of an artery 17, while being retained against movement in an opposite direction.

Each occluder 11, 13 is formed of a material and a shape so as to be circumferentially collapsible, for example from the normal position shown in Figs. 9 and 10. Further, each occluder 11, 13 is made to be resiliently expandable from a collapsed state into the normal positions as shown in Figs. 9 and 10.

As shown in Fig. 9, the intra-arterial occluder 11 is of circular disc shape and is provided with a plurality of radial struts 18 integral with flexible sections 19 therebetween.

As shown in Fig. 10, the extra-arterial occluder 13 of umbrella-like construction having a plurality of radially disposed struts 20 with integral web-like sections 21 therebetween. Further, the struts 20 extend radially outwardly of the web portions 21 so as to engage the tissue outside of the vessel 17 (see Fig. 7) to encourage circumferential opening of the occluder 13.

As indicated in Figs. 9 and 10, the extra-arterial 13 is of larger outer dimensions than the intra-arterial occluder 11.

Both occluders 11, 13 are made of a suitable biocompatible material which may as well be a bioabsorbable material so as to be absorbed over time. In this respect, the rate of absorption of the intra-arterial occluder 11 is faster than that of the extra-arterial occluder 13 and the guide 12 to reduce the risk of the intra-arterial occluder 11 coming free.

Referring to Figs. 7 and 8, the sealing device 10 is constructed such that the intra-arterial occluder 11 can be placed on the inside of the vessel 17 over an opening or puncture 22 therein while the extra-arterial occluder 13 secured over the outside of the vessel 17 on the opposite side of the opening 22. The degree of pressure between the occluders 11, 13 should be sufficient to seal the opening 22 while at the same time not creating undue pressure on the wall 16 of the vessel 17.

Referring to Fig. 6, the insertion tool 23 is constructed so as to facilitate implantation of the sealing device 10. As illustrated, the tool 23 includes a barrel 24, a handle 25 which is fixed to one end of the barrel 24, a positioner member 26 which is slidably mounted in the barrel 24 to define a chamber 27 at one end for receiving the extra-arterial occluder 13 and a trigger 28 which is pivotally mounted on the handle 25 with one end disposed in the barrel 24. As indicated, the trigger 28 is mounted via a pivot pin 29 which is fixed within a yoke 30 integral with the handle 25.

In addition, a stem or extension 31 extends from the positioner 26 into a recess 32 in one end of the trigger 28 and is provided with an enlarged head 33 within the recess 32. As illustrated, the entrance to the recess 32 is formed by a pair of projections 34 which serve to define a slot through which the extension 31 may pass while preventing outward passage of the enlarged head 33. For purposes of assembly, the projections 34 may be sufficiently flexible to permit introduction of the head 33 or may be formed as separate pieces which are removably secured to the trigger 28 in a suitable fashion to permit assembly of the head 33 within the recess 32.

The extension 31 and head 32 serve as a means for pushing the positioner member 26 in a direction out of the barrel 24 in order to expel the extra-arterial occluder 13 therefrom.

A spring wire 35 is also mounted in the trigger 28 to extend through the recess 32 and upwardly, as viewed, through an appropriate slot in the barrel 24 for purposes as described below. The spring wire 35 abuts against the head 33 on the stem 31 so as to transfer a pushing force on the head 33 and thus the positioner member 26 so as to push the member 26 in a direction out of the barrel 24 in order to expel the extra-arterial occluder 13, therefrom.

The positioner member 26 is hollow so as to define a through bore 36 for passage of the guide 12 therethrough. In addition, a clamp 37 is provided within the handle 25 for selectively clamping the guide 12 passing therethrough in response to pivoting of the trigger 28 and prior to movement of the positioner member 26. As indicated, a means is provided between the trigger 28 and the clamp 37 in order to effect a clamping action. This means includes a guide clamp actuator 38 which is pivotally mounted at one end on a pivot pin 39 secured to the trigger 28. In addition, the actuator 38 is slidably mounted within a recess 40 of the handle 25 and has a recess 41 which contains a cam surface 42 which rides on a fixed pin 43 in the handle 25. In addition, the actuator 38 carries one jaw 44 of the clamp 37 in facing relation to a second jaw 45 of the clamp 37 which is integral with the handle 25. As indicated, each jaw 44, 45 has a plurality of serrations 46 to grip the guide 12.

Upon pivoting of the trigger 28 in a clockwise direction, as viewed, the actuator 38 is slid to the right relative to the jaw 44 and raised via the pin 43 thereby bringing the jaws 44, 45 together about the guide 12.

The tool 23 is also provided with a force gauge 47 on the barrel 24 for indicating a degree of pressure exerted on the clamped guide 12 during movement of the positioner member 26 relative to the guide 12. This force gauge 47 is calibrated in pressure units of millimeters of mercury to reflect the force applied to the surface area of the intra-arterial occluder 11 (see Fig. 7). It is expected that the pressure applied by the operator will be between diastolic and just above systolic blood pressure although the optical pressure necessary should be determined from clinical trials.

The force gauge 47 is constructed as an L-shap-

ed element which is mounted on the end of the trigger 28 and which projects through a slot in the barrel 24. In addition, the exposed leg 48 of the gauge 47 carries a printed calibrated scale (not shown) which is coordinated with the spring wire 35 so as to provide a read out of the force applied to the spring wire 35 during pivoting of the trigger 28 in a clockwise Figmanner as viewed. As indicated in 6, a pair of slots 49 may be provided in the barrel 24, one for the spring wire 35 and one for the gauge 47.

As shown in Fig. 6, the distal end of the barrel 24 is provided with a flexible tip 50 while the positioner member 26 is provided with a flexible tip 51. This permits the tool 27 to bend at the end when the extra-arterial occluder 13 is being implanted.

By way of example, the flexible tip 50 of the barrel 24 may be effected by parallel slots which are cut into the barrel 24 from opposite sides without reaching the mid-line of the barrel 24. This allows the barrel to bend in a plane parallel to the handle 25 of the tool 24. In like manner, the flexible tip 51 of the positioner member 26 may be formed with slots of the same nature. In addition, the surface of the barrel 24 and the positioner member 26 can be lined with a flexible and deformable material which will allow them to slide past each other without undue resistance.

In addition, a cutting means 52 is provided for severing the guide 12 within the positioner member 26 in response to retraction of the member 26 into the barrel 24 after implanting of the extra-arterial occluder 13. As indicated, this cutting means 52 includes a pair of pincers 53 in the flexible positioner tip 51 on opposite sides of the bore 36, a cam surface 54 within a groove 55 of the positioner 26 and a cam 56 fixedly mounted on the inside wall of the barrel 24 for slidably engaging the cam surface 54 in order to radially deform the flexible positioner tip 51 so as to effect closing of the pincers 53 together with sever the guide 12 therebetween.

Referring to Fig. 1, in order to seal the opening 22 in the artery 17, for example at the end of an arteriographic procedure, a percutaneous sheath 57 which is normally used in that procedure is retained in place. The intra-arterial occluder 11 which when deployed is larger than the anticipated opening 22, together with the guide 12 is pushed through the sheath 57 into the lumen of the artery 17 by an obturator (not shown). As the occluder 11 exits the sheath 57, the occluder 11 resiliently expends to full size.

Next, referring to Fig. 2, the intra-arterial occluder 11 is pulled back against the inside wall of the artery 17 and the sheath 57 removed.

Next, the insertion tool 23 is slid over the guide 12. At this time, the collapsed extra-arterial occluder 13 nests in the chamber 27 (see Fig. 6) of the tool 23 while the guide 12 passes through the extra-arterial occluder 13 and through the entire tool 23.

When the trigger 28 on the tool 23 is activated, two sequential functions occur, one after the other. First, the guide 12 is clamped in place relative to the tool 23 via the clamp 37. In this respect, during initial travel, the trigger 28 moves the clamp actuator 38 forwardly, i.e., to the right as shown in Fig. 6. The actuator 38 then translates upwardly to force the clamp jaws 44, 45 (or other high friction mechanism) together in order to fix the guide 12 in place. During this part of the trigger movement, there is no movement of the positioner member 26.

Next, as the trigger 28 continues to pivot, the end of the trigger 28 pushes the spring wire 35 in contact with the enlarged head 33 and, thus, the positioner member 26. The spring wire 35 then deforms toward the rear of the tool in proportion to the force applied as the positioner member 26 moves forwardly to expel the extra-arterial occluder 13 (Fig. 3). The force which is applied to the positioner member 26 is resisted by the guide 12 which is fixed in place by the guide clamp 37. The resisting force is transmitted through the guide 12 to the intra-arterial occluder 11 which is being pressed against the inner surface of the arterial wall. The force applied divided by the known surface area of the intra-arterial occluder 11 yields the pressure exerted against the wall of the artery by the intra-arterial occluder. This pressure is registered on the calibrated scale printed on the force/pressure gauge 47.

As the travel of the trigger 28 continues, the extra-arterial occluder 13 is advanced along the guide 12 until exiting the tool 23. Thereafter, an increase in spreading force is applied between the extra-arterial occluder 13 and the fixed guide 12 (see Fig. 4). The force on the guide 12 and the positioner member 26 which is registered on the force gauge 47 is effectively transmitted to the intra-arterial occluder 11. As pressure is applied, the flexible tip 50 of the barrel 24 and the flexible tip 51 of the positioner member 26 conform to a shape perpendicular to the wall 16 of the vessel 17 (see Fig. 4).

Once the extra-arterial occluder 13 is positioned, the guide 12 is severed. To this end, the trigger 28 is pivoted in a reverse direction, i.e. counterclockwise as viewed in Fig. 6, so as to retract the positioner member 26 into the barrel 24. To this end, the trigger 28 is provided with a cut-out 57 to accommodate the fingers so that the trigger 28 is easily pulled away from the handle 25.

As the positioner member 26 retracts, the cam 56 engages the cam surface 54 of the flexible positioner tip 51 causing the pincers 53 to come together. The pincers 53 then exert a sufficient force to sever the guide 12 thereat. Since the cutting operation occurs within the positioner member 26, there is little danger of cutting the guide 12 too short which could inadvertently allow the intra-arterial and extra-arterial occluders 11, 13 to separate.

The insertion tool 23 is then removed from the

patient and a band-air or similar dressing is applied to the wound.

Of note, the occluders 11, 13 may be held together at the desired pressure other then through the use of the guide saw teeth 46. For example, glues may be used.

The invention thus provides a sealing device which is fixedly secured in place completely internal in the patient. There are no external members which may leave a path for infection into the patient. Further, sealing device may be used to close percutaneous punctures in any number of body parts including, but not limited to, the gall bladder, stomach, intestine, lung, heart, urinary bladder, urinary collecting systems veins.

Further, the invention provides a tool which can be readily manipulated to implant a sealing device totally within a patient.

Further, the invention provides a relatively simple tool for the deployment of a sealing device about an opening in body tissues.

Still further, the invention provides a tool which is capable of measuring the occluder pressure during insertion.

Claims

1. A sealing device comprising a first member (11) for positioning on one side of a puncture in a tissue for closing over the puncture, and a guide means (12) extending from the first member (11) for passage through the puncture, the first member (11) being circumferentially collapsible for passage through the puncture and resiliently expandable; characterized in that there is also provided a second member (13) on the guide means (12) for positioning on the opposite side of the puncture to seal the puncture, the second member (13) being resiliently expandable from a circumferentially collapsible state.

2. A sealing device as claimed in claim 1, wherein the first member (11) and the second member (13) are made of at least one of a biocompatible material and a bioabsorbable material.

3. A sealing device as claimed in claim 1, wherein both the first member (11) and the second member (13) are made of bioabsorbable material and the first member (11) has a faster rate of absorption than said second member (13).

4. A sealing device as claimed in claim 1, 2 or 3, wherein at least one of the first and second members (11, 13) includes at least one of an antithrombotic material and a clot-promoting material therein.

5. A sealing device as claimed in any preceding claim, wherein the guide means (12) is a guide wire.

6. A sealing device as claimed in claim 5, wherein the guide wire (12) has a portion containing a plurality of teeth (14) inclined to tend to prevent the second member (13) against movement in a direction away from the first member (11).

7. A sealing device as claimed in any preceding claim, wherein the second member (13) is of larger outer dimensions than the first member when in the expanded condition.

8. In combination, a sealing device as claimed in any preceding claim, and a seal insertion tool for use in placing the second member (13) against the opposite side of the puncture, the seal insertion tool comprising:

   a barrel (24);

   a handle (25) fixed to one end of the barrel (24);

   a positioner member (26) slidably mounted in the barrel (24); and

   a trigger (28) pivotally mounted with respect to the handle (25);

   wherein the positioner member (26) partially defines a chamber (27) at one end of the barrel (24) to receive the resiliently expandable second member (13) which may serve as an extra-arterial occluder, and the trigger (28) has one end disposed in the barrel (24); and

   wherein there are means (31, 32) in the barrel (24) between the one end region of the trigger (28) and the positioner member (26) for pushing the second member (13) in a direction out of the barrel (24) in response to pivoting of the trigger (28) to expel the second member (13) therefrom.

9. A combination as claimed in claim 8, wherein the positioner member (26) is hollow to define a bore (36) for passage of an elongated guide means (12) which is preferably a guide wire, extending from the first member (11) which may serve as an intra-arterial occluder (13), through the extra-arterial occluder or other second member (13); and wherein there is a clamp (37) within the handle (25) for passage of the guide wire therethrough and for selectively clamping the guide wire (12) in response to pivoting of the trigger (28) prior to movement of the positioner member (26) in the barrel (24).

10. A combination as claimed in claim 9, which fur-

ther includes a force gauge (47) on the barrel (24) for indicating a degree of pressure exerted via the clamped guide wire (12) on the intra-arterial occluder or other first member (11) at an end of the wire during movement of the positioner member (26) relative thereto.

11. A combination as claimed in claim 9 or 10, which further includes a cutting means (52) for severing the guide wire (12) within the positioner member (26) in response to retraction of the positioner member (26) into the barrel (24).

12. A combination as claimed in claim 11, wherein the cutting means (52) includes a pair of pincers (53) in the positioner member (26) disposed on opposite sides of the bore (36), a cam surface (54) on the member (26) and a cam (56) on the barrel (24) for slidably engaging the cam surface (54) to radially deform the positioner member (26) to effect closing of the pincers (53) together to sever the guide therebetween.

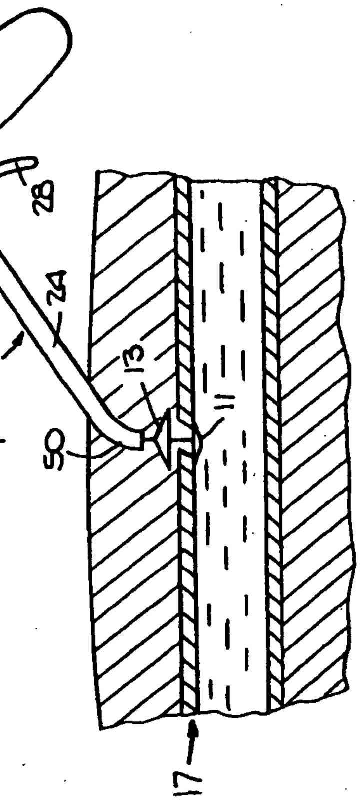

Fig. 3.

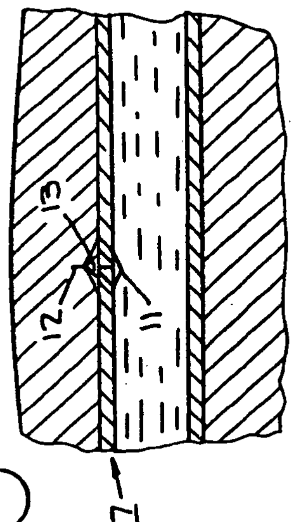

Fig. 5.

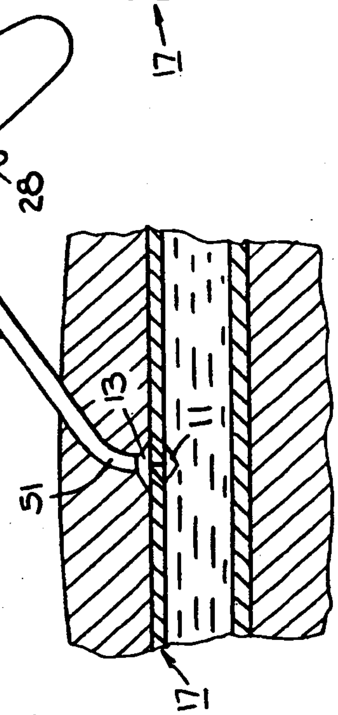

Fig. 4.

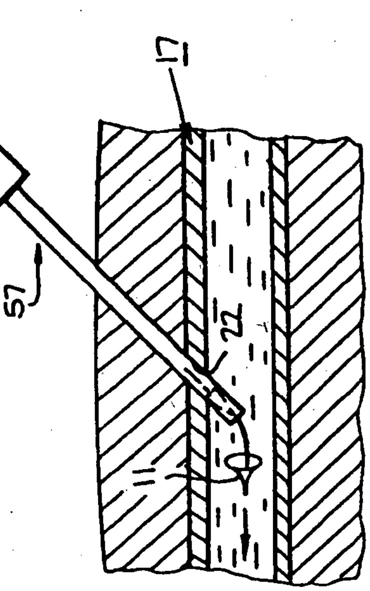

Fig. 1.

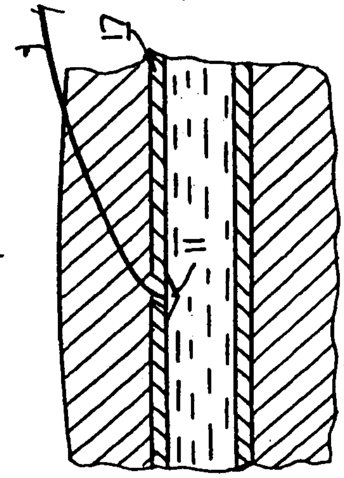

Fig. 2.

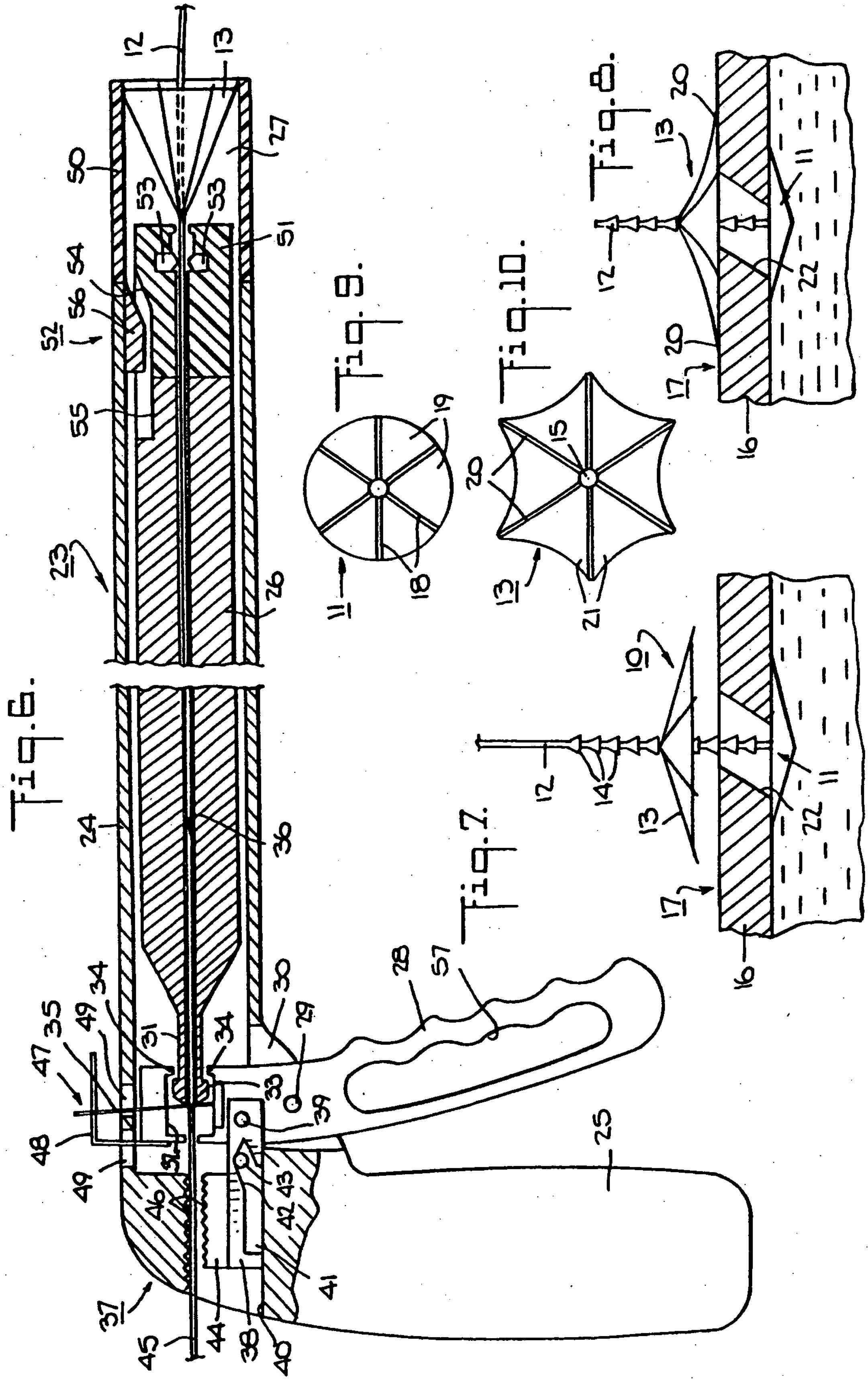
Fig.6.
Fig.7.
Fig.8.
Fig.9.
Fig.10.

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 92 30 8566

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	US-A-3 874 388 (KING ET AL.) * column 6, line 8 - line 60 * * column 9, line 9 - column 10, line 16; figures 1A-C,9A-K *	1,2,4,5, 8,10	A61B17/00 A61B17/12
X	WO-A-9 014 796 (MUIJS VAN DE MOER) * page 4, line 12 - page 5, line 15; figures 3,4,6 *	1,2,4,5, 6	
A	WO-A-9 116 858 (KENSEY NASH) * page 10, line 3 - line 32 * * page 15, paragraph 2 - page 17, paragraph 1 * * page 18, paragraph 2; figures 1,2,4-7 * & US-A-5 021 059 4 June 1991	8-10	
A	EP-A-0 362 113 (SIDERIS) * column 5, line 4 - line 21; figure 8 *	11	**TECHNICAL FIELDS SEARCHED (Int. Cl.5)**
A	US-A-4 078 305 (AKIYAMA) * abstract; figures 4-6 *	11	A61B A61F
A	JP-A-54 009 482 (...) * figure 1 *	6	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	22 DECEMBER 1992	MOERS R.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

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(54) Surgical apparatus and method for marking tissue location

(57) A surgical apparatus for marking a location within tissue which includes (i) a needle including a housing and an elongated tube having a sharp distal end, (ii) an elongated cable configured and dimensioned to pass through a longitudinal passageway formed through the needle, (iii) an elongated tissue marker attached adjacent a distal end of the elongated cable such that the elongated marker is movable between a retracted orientation and a deployed orientation, and (iv) an actuator assembly operatively associated with the elongated marker, wherein movement of the actuator assembly from a first position to a second position moves the elongated marker from the retracted position to the deployed position. A method of marking a particular location in body tissue is also provided, which includes the steps of (i) inserting an apparatus into a section of body tissue, (ii) deploying an elongated marker having an elongated cable attached thereto from the apparatus into the tissue, (iii) retaining the elongated cable relative the distal end of the apparatus, and (iv) moving the elongated marker into an orientation substantially perpendicular to the elongated cable.

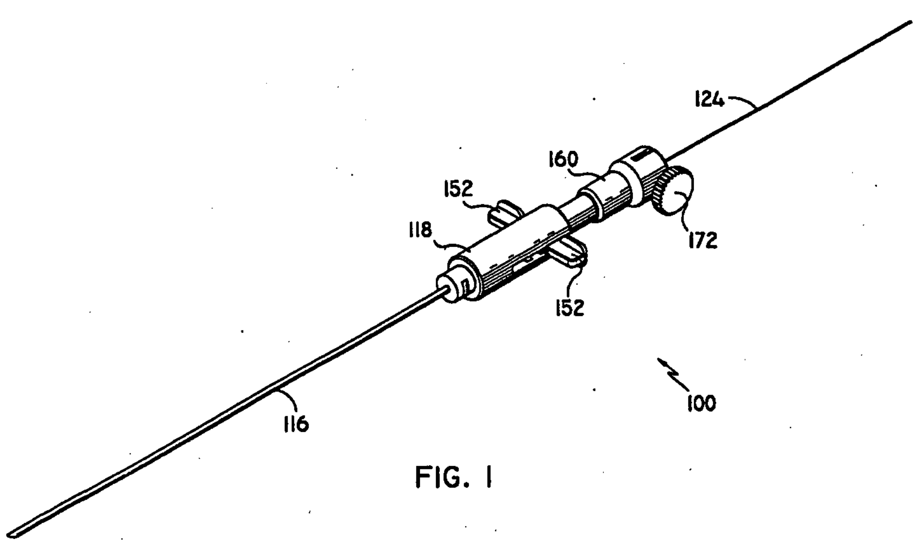

FIG. 1

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Description

BACKGROUND

1. Technical Field

The present disclosure relates generally to tissue marking apparatus and method for identifying a particular location within a mass of body tissue.

2. Background of Related Art

Marking specific locations within body tissue, such as non-palpable lesions discovered within the body, and devices such as needles and wires for marking these lesions, are well known in the art. Such devices generally comprise a hypodermic needle or cannula which is inserted into the body and positioned adjacent to or in contact with the lesion. A wire marker is then passed through the needle or cannula and is anchored to the lesion marking it for subsequent surgical procedure, for example, excision or biopsy. Once the lesion is marked, the cannula is usually removed from the body, leaving the wire in place protruding from the body.

One of the most common procedures in which suspect tissue is marked is to locate potentially cancerous lesions found within a female patient's breast tissue. In such procedures, the subject breast is typically compressed during a mammographic tagging procedure. With some of the known devices, after the tissue marker is in place and compression discontinued, it is possible that the marker may dislodge or migrate from the position set during the tagging procedure.

Various tissue marking systems have been proposed to aid in locating non-palpable lesions within the breast and to prevent inadvertent dislodgment and/or migration of the needle. One such system includes a cannula needle and a wire guide made of a shape memory characteristic material which assumes a J-hook configuration. Such a device may be found, for example, in U.S. Patent No. 5,011,473 to Gatturna which discloses a needle inserted into the breast and advanced to identify the location of a lesion. Gatturna discloses a wire which is advanced inwardly allowing a J-hooked end to engage body tissue and immobilize the needle.

Devices utilizing such J-hook systems, however, have been unable to solve the problem of preventing migration of the tissue marker. For example, in such devices, the tissue marker can be displaced if pressure is applied to the breast during transportation of the patient to the surgical suite or during preparation of the patient for surgery. Also, if the strength or resiliency of the wire is less than that required to penetrate the lesion, the hook may not reform, allowing the marker to migrate.

Another example of existing tissue marking devices, referred to as a needle and hook-wire system, may be found in U.S. Patent No. 5,158,084 to Ghiatas. Ghiatas discloses a tissue-marking needle system which includes a stainless steel wire having a hairpin hooked-end. Similar to the J-hook system, the needle is inserted into the breast tissue to locate the lesion and the wire is slid through the needle thereby engaging the body tissue and anchoring the wire at lesion's location.

In such devices, however, compression of the breast, e.g., as routinely done during mammographic filming of the breast, may result in migration or displacement of the needle. Although the hook will tend to prevent outward movement of the wire, it is not designed to prevent advancement of the wire further into the patient's breast tissue.

Accordingly, a need exists for an improved tissue marking apparatus which overcomes the above-noted limitations of existing tissue marking devices, is easy to use and provides more reliability when marking suspect tissue.

SUMMARY

The present disclosure provides a surgical apparatus and a method for marking a particular location in body tissue, which addresses the limitations associated with conventional tissue marking devices. Additionally, the present disclosure provides a surgical apparatus for marking a location within tissue which may be used in both minimally invasive as well as open surgical procedures.

One embodiment of the present disclosure provides a surgical apparatus for marking a location within tissue, such apparatus including (i) a needle including a housing and an elongated tube having a sharp distal end, (ii) an elongated cable configured and dimensioned to pass through a longitudinal passageway formed through the needle, (iii) an elongated tissue marker attached adjacent a distal end of the elongated cable such that the elongated marker is movable between a retracted orientation and a deployed orientation, and (iv) an actuator assembly operatively associated with the elongated marker, wherein movement of the actuator assembly from a first position to a second position moves the elongated marker from the retracted position to the deployed position.

In a preferred embodiment, when the elongated marker is in the retracted position, a longitudinal axis of the elongated marker is substantially parallel to a longitudinal axis of the elongated cable. Additionally, when the elongated marker is in the deployed position, the longitudinal axis of the elongated marker is substantially perpendicular or transverse to the longitudinal axis of the elongated cable.

In an alternative embodiment, the elongated marker is movable between (i) a retracted position, wherein the elongated marker forms a substantially uniform transverse dimension, and (ii) a deployed position, wherein the elongated marker has a transverse dimension which is substantially greater than that of the outer surface of the elongated needle tube. Preferably, in the retracted position, the elongated marker includes an

outer surface which is in substantial alignment with the outer dimension of the elongated needle tube which is used to introduce the elongated marker to the target tissue.

Preferably, the actuator assembly includes a first deployment actuator operatively connected to the housing and a second deployment actuator operatively associated with the first deployment actuator. The actuator assembly also preferably includes an advancing tube disposed between the first deployment actuator and the elongated marker.

The present disclosure also provides a surgical apparatus for marking a particular location in body tissue, which includes (i) a needle defining a longitudinal passageway therethrough, (ii) an elongated cable configured and dimensioned to pass through the longitudinal passageway, (iii) an elongated marker attached adjacent a distal end of the elongated cable such that the elongated marker is movable between a retracted orientation and a deployed orientation, and (iv) a stabilizer member which is moved from a first position relative to the elongated cable and the elongated marker, to a second position in operative association with the elongated cable and the elongated marker to maintain the elongated marker in the deployed orientation. The apparatus preferably also includes a stop member disposed on the elongated cable at a point proximal of the elongated marker, wherein the stabilizer member is disposed between the elongated marker and the stop member, such that the elongated cable is held in tension between the stop member and the elongated marker. Preferably, the stop member is a ferrule which is attached to the elongated cable member.

A clamp is also disclosed herein which is operatively associated with the elongated cable to selectively prevent longitudinal movement of the elongated cable relative to the needle. The clamp preferably includes a screw movable from a first position, which permits longitudinal movement of the elongated cable relative to the apparatus housing, to a second position, which prevents longitudinal movement of the elongated cable relative to the apparatus housing.

The present disclosure also provides an apparatus for marking a particular location in body tissue, which includes (i) a housing, (ii) an elongated cable configured and dimensioned to pass through a longitudinal passageway defined by the housing, (iii) a tissue marker operatively connected to a distal end of the elongated cable, such that movement of the elongated cable from a first position to a second position moves the marker from a retracted orientation to a deployed orientation, and (iv) a clamp operatively associated with the elongated cable to selectively prevent longitudinal movement of the elongated cable relative to the apparatus housing.

The clamp preferably includes a body portion defining a passageway therethrough to receive the elongated cable and a bias member movable from a released position, wherein the elongated cable is permitted to move longitudinally relative to the body portion and a clamped position, wherein the elongated cable is prevented from moving longitudinally relative to the body portion.

The present disclosure also provides a surgical apparatus for marking a particular location in body tissue, which includes (i) a needle assembly including a housing and an elongated tube having a sharp distal end, (ii) a marker assembly including an elongated cable configured and dimensioned to pass through a longitudinal passageway defined by the needle assembly, and an elongated tissue marker attached adjacent a distal end of the elongated cable such that the elongated marker is movable between a retracted orientation and a deployed orientation, wherein the elongated cable is sufficiently rigid to maintain the elongated tissue marker in each of said retracted and deployed orientations, and (iii) an actuator assembly operatively associated with the elongated marker, wherein movement of the actuator assembly from a first position to a second position moves the elongated marker from the retracted position to the deployed position.

The present disclosure also provides a method of marking a particular location in body tissue which includes the steps of (i) inserting an apparatus into a section of body tissue, (ii) deploying an elongated marker having an elongated cable attached thereto from the apparatus into the tissue, (iii) retaining the elongated cable relative to the distal end of the apparatus, and (iv) moving the elongated marker into an orientation substantially perpendicular to the elongated cable.

The method may further include the step of fixing the orientation of the marker in the deployed orientation.

Preferably the step of retaining the elongated cable includes clamping the elongated cable to a portion of the apparatus.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments are described herein with reference to the drawings, wherein:

FIG. 1 is a perspective view of one embodiment of the apparatus for marking a particular location in body tissue constructed in accordance with the present disclosure;

FIG. 2 is a perspective view, with parts separated, which shows the individual structural components of the embodiment of FIG. 1;

FIG. 3 is a partial perspective view, with parts separated, which shows the distal end of the cable of the embodiment of FIG.1 and the positioning of the tissue marker thereon;

FIG. 4 is a perspective view similar to FIG. 3, which shows the tissue marker crimped in place on the

distal end of the cable;

FIG. 5 is a perspective view of the distal end of the apparatus embodiment of FIG. 1, which shows the relative positioning of the cable and tissue marker within the needle of the embodiment of FIG. 1;

FIG. 6 is a partial perspective view showing the proximal end of the embodiment of FIG. 1;

FIG. 7 is an enlarged view of the indicated area of detail of FIG. 6;

FIG. 8 is a partially cut-away perspective view which shows the internal working surfaces of the actuator housing;

FIG. 9 is an enlarged partially cut-away view of the indicated area of detail of FIG. 6;

FIG. 10 is a perspective view, which shows the insertion of the embodiment of FIG. 1 in the tissue of a patient to the location of the suspect tissue;

FIG. 11 is a partial cross-sectional view of the proximal end of the embodiment of FIG. 1;

FIG. 12 is a view similar to FIG. 11, showing actuator assembly deployment of the embodiment of FIG. 1;

FIG. 13 is a partially cut-away perspective view of the distal end of the embodiment of FIG. 1, which shows the corresponding movement of the tissue marker from a distal end of the apparatus as effected by the movement of the actuator assembly indicated in FIG. 12;

FIG. 14 is a perspective view of the proximal end of the apparatus which corresponds to the view of FIG. 12;

FIG. 15 is a longitudinal cross-section view of the proximal portion of the embodiment of FIG. 1, which shows the movement of the various operational components involved in deploying the tissue marker to its fully rotationally deployed position;

FIG. 16 is a perspective view of the proximal end of the embodiment of FIG. 1, which corresponds to the view shown in FIG. 15;

FIG. 17 is a perspective view of the distal end of the embodiment of FIG. 1, which shows the initial distally deployed position of the tissue marker immediately before rotational deployment thereof;

FIG. 18 is a view similar to FIG. 17, which shows the initial rotational deployment motion of the tissue marker;

FIG. 19 is a view similar to FIGS. 17 and 18, which shows the complete rotational deployment of the tissue marker;

FIG. 20 is a view similar to FIG. 10, which shows the tissue marker in its full rotationally deployed position within the suspect tissue lesion;

FIG. 21 is a longitudinal cross-sectional view of the proximal end of the embodiment of FIG. 1, which shows the release of the clamping mechanism on the cable;

FIG. 22 is a view showing the marker and cable in place in the suspect tissue lesion with the marking apparatus removed therefrom;

FIG. 23 is a perspective partially cut-away view, with parts separated, which shows the relationship of the crimped ferrule positioned on the cable and the stabilizing tube;

FIG. 24 is an enlarged view of the indicated area of detail of the distal of the stabilizing tube as indicated in FIG. 23;

FIG. 25 is a cross-section view taken along section line 25-25 of FIG. 23;

FIG. 26 is a cross-section view similar to FIG. 25, which shows the insertion of the stabilizing tube over the cable and crimped ferrule;

FIG. 27 is a broken longitudinal cross-sectional view, which shows the stabilizing tube in position between the ferrule member and the tissue marker;

FIG. 28 is a view similar to FIG. 22, which shows the stabilizing tube in place;

FIG. 29 is an enlarged view of the indicated area of detail shown in FIG. 28;

FIG. 30 is enlarged view of the fully deployed marker as shown in the indicated area of detail of FIG. 28;

FIG. 31 is a perspective view of a further embodiment of an apparatus for marking a particular location in body tissue constructed in accordance with the present disclosure;

FIG. 32 is an enlarged view of the distal end of the embodiment of FIG. 31 as indicated by the area of detail in FIG. 31;

FIG. 33 is a perspective view with parts separated,

which shows various components of the embodiment of FIG. 31;

FIG. 34 is a broken, longitudinal cross-sectional view of the embodiment of FIG. 31;

FIG. 35 is a perspective view, which shows the distal end of the embodiment of FIG. 31 with a portion of the advancing tube partially cut away;

FIG. 36 is a broken, longitudinal cross-sectional view showing the deployment of the tissue marker; and

FIG. 37 is a perspective view similar to FIG. 35, which shows the deployment of the marker as corresponds to FIG. 36.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Preferred embodiments of the presently disclosed tissue marking apparatus will now be described in detail with reference to the drawings, in which like reference numerals designate identical or corresponding elements throughout each of the several views. Referring initially to FIGS. 1 and 2, one embodiment of an apparatus for marking a particular location in body tissue in accordance with the present disclosure is exemplified by tissue marker apparatus 100. Tissue marker apparatus 100 is particularly adapted for use in minimally invasive surgical procedures to mark the location of targeted or suspect tissue.

The presently disclosed tissue marker apparatus embodiments are illustrated as utilized to locate lesions formed within the tissue of a female breast as identified by known imaging processes, e.g., stereotactic imaging. However, it will be understood by those skilled in the art that the presently disclosed tissue marker apparatus embodiments may also be utilized to locate targeted or suspect tissue in other areas of the body as well.

Except where noted otherwise, the materials utilized in the components of the presently disclosed embodiments of apparatus for marking particular locations in body tissue generally include materials such as polycarbonate for housing sections and related components and stainless steel for components that are required to cut tissue. A preferred polycarbonate material is available from General Electric under the trademark LEXAN.

Generally, tissue marker apparatus 100, when assembled into its three principle subassemblies, includes a needle assembly 110, a marker assembly 112, and an actuator assembly 114, as described in detail further herein.

As shown in FIG. 2, needle assembly 110 includes a hollow, preferably stainless steel, shaft 116 having a barrel-shaped body portion 118 mounted at a proximal end and a sharpened hollow tip 119 formed at a distal end. Body portion 118 preferably has a stepped throughbore 120 (FIG. 8) to securely receive shaft portion 116, e.g., by friction fit, which may be supplemented by bonding, adhesives or the like. Body portion 118 is further provided with a transverse slot 122 which is open at the proximal end surface of body portion 118. The significance of transverse slot 122 and the various control surfaces formed thereon are described in detail further herein.

Referring now to FIG. 2A through FIG. 5 in conjunction with FIG. 2, marker assembly 112 includes a cable 124, a stop member in the form of a ferrule 126 crimped around cable 124 at a predetermined distance from the distal end (as is explained further herein), and a tissue marker 128 crimped about the distal end portion 130.

As best illustrated in FIG. 3, tissue marker 128, in a preferred configuration, is formed to have an elongated longitudinal U-shaped channel 132 forming a pair of opposed flanges 134a and 134b. A notch 136 is formed at approximately the mid-point of flange 134a to facilitate the crimping of tissue marker 128 about the distal end portion 130 of marker 124. Tissue marker 128 could also have alternative configurations which would also facilitate its attachment to cable 124. For example, the distal end portion of tissue marker 128 could be preformed to have a hollow cylindrical configuration. The tissue marker could then be attached to cable 124 by, for example, swaging or welding.

Distal end portion 130 of cable 124 is provided with a series of bends to form elbows 138a, 138b, 140a, and 140b to accommodate marker assembly 112 within needle shaft 116, as shown in FIG. 5, and to facilitate deployment of tissue marker 128. Elbows 138a and 138b offset cable segment 142 a predetermined distance "X", as indicated in FIG. 3, from a proximal segment 144 of cable 124.

Thus, when tissue marker 128 is fitted over distal end portion 130 of cable 124, the portion of tissue marker 128 proximal of notch 136 is disposed entirely on one side of cable segment 142, as shown in FIG. 4. Elbows 140a and 140b offset cable segment 146 a predetermined distance "Y" from proximal cable segment 144. Distance "Y" is preferably less than distance "X", such that cable segment portion 146 fits within elongated U-shaped channel 132 and flange portions 134a and 134b are crimped about segment 146 as shown in FIG. 4. Distances "X" and "Y" are predetermined such that upon assembly with cable 124 tissue marker 128 is substantially parallel to proximal cable segment 144 the assembled cable 124 and tissue marker 128 fit within the internal diameter of needle shaft 116, as shown in FIG. 5.

Actuator assembly 114 will now be described with reference to FIG. 2 in conjunction with FIGS. 6-8. A plunger 148 is provided which includes a longitudinal throughbore formed therein. An elongated advancing tube 150 is preferably friction fitted in the distal end of the throughbore of plunger 148. Alternatively, advancing tube 150 may be secured in the throughbore of plunger

148, for example, by bonding, adhesives, sonic welding or the like.

Plunger 148 is preferably provided with transversely extending deployment arms 152. A pair of bearing surfaces 154 are formed on the proximal surface of deployment arms 152 and are preferably configured and dimensioned to facilitate ergonomic distal movement of plunger 148. For example, bearing surfaces are preferably formed to be comfortably engaged by a finger of the user. Thus deployment arms may be moved distally by the user applying pressure on bearing surfaces 154 with a finger or fingers. Plunger 148 is further provided with a reduced diameter portion 156 extending from a proximal end and having threads 158 formed at the proximal end thereof. Threads 158 engage internal threads 162 formed along the distal end inner surface of a stepped throughbore formed in marker deployment actuator 160.

A cable clamp mechanism is also provided on marker deployment actuator 160 and includes a U-shaped stainless steel clip 164 which is fitted in a transversely extending slot 166 which is open at the proximal end surface of marker deployment actuator 160. A clamp set-screw 168 also forming part of the clamp mechanism is provided to be threadably received in a threaded bore 170 formed through marker deployment actuator 160. Threaded bore 170 is formed transverse to slot 166 and extends from an inner wall of slot 166 to the outer longitudinal surface of marker deployment actuator 160. The significance of the clamp mechanism will be described in further detail herein. Preferably, clamp set screw 168 is provided with a knurled dial 172 attached to threaded portion 174 to facilitate actuation of the clamping mechanism upon rotation of knurled dial 172 by the user.

Referring temporarily back to FIG. 5, an abutment member 176, which also forms part of the actuator assembly 114, is slidably positioned on cable 124 between distal end portion 130 and crimped ferrule 126. Abutment member 176 is preferably formed as an elongated cylindrically shaped element having a longitudinal throughbore formed therein. The wall thickness of abutment member 176 is preferably greater than the wall thickness of advancing tube 150. Additionally, the throughbore of abutment member 176 is dimensioned to be only slightly greater than the outer diameter of proximal cable segment 144. For example, a suitable tolerance between the throughbore of abutment member 176 and the outer diameter of proximal cable segment 144 is approximately .01-.05 mm. This dimensional relationship between the throughbore of abutment member 176 and proximal cable segment 144 facilitates the rotational deployment of tissue marker 128 while providing additional stability, as will be described further herein.

Actuator assembly 114 is advantageously designed to provide a two-stage actuation to place tissue marker 128 at the desired location. In the first stage, plunger 148 is moved distally to longitudinally deploy tissue marker 128 and cable 124 from the distal end of needle shaft 116. In the second stage, proximal cable segment 144 is clamped to marker deployment actuator 160 by clamp set-screw 168 and marker deployment actuator 160 is moved proximally, for example, by rotating marker deployment actuator 160 relative to plunger 148 so as to separate the two components. This motion pulls cable 124 and tissue marker 128 proximally with respect to abutment member 176. Alternatively, marker deployment actuator 160 may be slidably disposed relative to plunger 148 to effectuate the desired proximal movement.

During the second stage of actuation, it is necessary to maintain plunger 148 in a fixed relationship relative to needle assembly 110. Accordingly, body portion 118 of needle assembly 110 is provided with several control surfaces to facilitate deployment of marker assembly 112 from the distal end of needle assembly 110 and to maintain the relative positioning of plunger 148 with respect to needle assembly 110.

Referring to FIGS. 6-8, body portion 118 is provided with a series of wedge-shaped stops formed along the inner surfaces 178 and 180 of transverse slot 122. A first group of stops 182 formed in opposing relationship at the same axial disposition along inner surfaces 178 and 180 establish the initial pre-deployed position of plunger 148 which corresponds to the fully retracted position of marker assembly 112 as shown in FIG. 5. Stops 182 additionally facilitate assembly of actuator assembly 114 into body portion 118. Camming action caused by arms 152 as plunger 148 is inserted in the open end of slot 122 until the proximal surface of arms 152 pass beyond the distal face of stops 182. Once arms 152 are inserted past stops 182, opposed barrel portions 184 and 186 snap back into place, thereby preventing proximal movement of plunger 148.

A second or intermediate group of stops 188 which are somewhat smaller than stops 182 are formed along inner surfaces 178 and 180 at the same axial disposition relative to each other. Stops 188 are spaced a distance distally from stops 182 such that arms 152 are disposed between the distal face of stops 182 and the proximal-most portion of stops 188. Plunger 148 is thereby maintained at the initial pre-deployment position of marker assembly 112, as shown in FIG. 5.

A third group of stops 190 are provided along the inner walls 178 and 180 at the same axial disposition relative to each other to define a second position for plunger 148 corresponding to a distally deployed orientation of marker assembly 112 (as shown in FIG. 13). Similar to stops 182 and 188, stops 190 are formed in the shape of a wedge to facilitate distal movement of plunger 148 by camming barrel portions 184 and 186 outwardly as arms 152 pass over stops 190. Once arms 152 pass beyond the distal faces of stops 190, barrel portions 184 and 186 return to their at rest configurations thereby preventing proximal movement of plunger 148 relative to barrel portion 118.

In use, as shown in FIGS. 10-22, tissue marker

apparatus 100, is inserted through the breast tissue 192 of a patient with its control surfaces initially configured as shown in FIGS. 10 and 11. Tissue marker apparatus 100 is inserted such that the distal end is positioned adjacent a suspect lesion 194. The exact location of lesion 194 may be identified by any suitable known imaging apparatus or process, such as by stereotactic mammographic imaging, as is known in the art.

As shown in FIGS. 12-14, marker assembly 112 is deployed from its initial position, through the first stage of deployment, i.e., distal movement to completely expose tissue marker 128 relative to the sharpened tip 119 of needle shaft 116. The exposure of tissue marker 128 is facilitated by applying a distally directed force to arms 152, as indicated by arrows "A" in FIG. 12. Marker assembly 112 is configured and dimensioned to reach its distal-most longitudinally deployed position when arms 152 abut against the bottom of slot 122. Stops 190 prevent plunger 148 and, therefore, advancing tube 150, abutment member 176 and finally tissue marker 128 from movement in a proximal direction once distally deployed.

Cable 124 and, therefore, marker assembly 112 are fixed with respect to marker deployment actuator 160 by applying the clamp mechanism provided on marker deployment actuator 160. Specifically dial 172 is rotated, as shown in FIG. 15, to advance set-screw 168 and clamp cable 124 between the sides of U-shaped clip 164.

The rotational deployment of tissue marker 128 is initiated by rotation of marker deployment actuator 160 relative to body portion 118, as indicated by arrows "B", FIG. 16, in a counterclockwise fashion to unthread deployment actuator 160 from body portion 118. This rotational movement imparts proximal movement, as indicated by arrow "C" in FIG. 16, of marker deployment actuator 160 and the clamped elongated cable 124 held therein. Marker assembly 112 is thereby pulled proximally with respect to the relatively fixed abutment member 176 as indicated by arrow "D" as shown in FIG. 17. Rotation of marker deployment actuator 160 will twist cable 124 which is preferably selected to have material characteristics which permit such twisting while maintaining the necessary tensile strength to hold tissue marker 128 in the fully deployed perpendicular position, as described below.

Upon continued rotation of marker deployment actuator 160 and proximal movement of marker assembly 112, cable 124 moves toward abutment member 176 so that elbows 138a and 138b (FIG. 5) are straightened due to the inner walls of the throughbore in abutment member 176 acting on the malleable cable 124. As shown in FIG. 18, once tissue marker 128 comes into abutment with the distal face of abutment member 176, continued rotation of marker deployment actuator 160, as shown in FIG. 16, causes tissue marker 128 to begin rotating in the direction indicated by arrow "E" shown in FIG. 18. This rotation is due to the offset parallel axial alignment of tissue marker 128 with respect to proximal segment 144 of cable 124 and abutment member 176.

Upon still further rotation of marker deployment actuator 160, tissue marker 128 becomes disposed perpendicular to abutment member 176, as shown in FIGS. 19 and 20, thereby preventing further rotation of actuator 160. The resistance to further rotation will provide indication to the user of the full deployment of tissue marker 128.

Once the marker assembly 112 is fully deployed as shown in FIGS. 19 and 20, the clamp mechanism may be released by unscrewing set screw 168 as shown in FIG. 21. With cable 124 released, apparatus 100 can be removed from cable 124 and the marker assembly 112 left in place as shown in FIG. 22.

The presently disclosed tissue marker apparatus 100 utilized in either a minimally invasive or an open biopsy procedure. In a minimally invasive procedure, the suspect tissue or lesion is preferably located by a stereotactic imaging apparatus and removed with a minimally invasive instrument used in conjunction with the stereotactic apparatus.

For example, the presently disclosed tissue marking apparatus 100 is designed to be used in conjunction with a minimally invasive breast biopsy device, such as is disclosed in currently pending, commonly assigned U.S. Patent Application Serial No. 08/525,450, filed on September 8, 1995 by Milliman et al., and commonly assigned, co-pending, U.S. Patent Application Serial No. ________________, concurrently filed herewith by Milliman et al., which is a continuation-in-part application of the former cited Milliman et al. application. The entire contents of each of these applications are hereby incorporated by reference. In such a minimally invasive biopsy procedure, the presently disclosed tissue marker apparatus 100 is deployed as set forth herein, the needle assembly 110 and actuator assembly 114 (except for the abutment member 176) are removed from the patient leaving the abutment member 176 and marker assembly 112 to mark the lesion location. Then the minimally invasive biopsy instrument embodiment adapted for use on a stereotactic imaging apparatus, as disclosed in the above-mentioned Milliman et al. applications, may be advanced into the breast using the cable 124 as a guide. The precision locating capabilities of the stereotactic imaging machine can then be used to insert the biopsy instrument to the appropriate depth prior to actuation of the tissue removal structure.

Alternatively, the presently disclosed tissue marker apparatus 100 may be utilized in an open breast biopsy procedure, i.e., a procedure wherein the patient will likely be taken into a surgical suite after the marker is deployed. In such a procedure the lesion may be located by any suitable imaging apparatus or process, for example stereotactic imaging or ultrasound. The tissue marker 128 is then deployed as set forth above, the needle assembly 110 and the actuation assembly 114 (except for abutment member 176) are removed from the patient, preferably before transporting the patient to the operative suite, if such transportation is necessary.

Marker assembly 112 is thereby left in place with the abutment member 176 disposed around cable 124 adjacent the perpendicularly disposed marker 128. When the patient is located in the operating room, a stabilizing tube 196 is provided such as the one shown in FIGS. 23-30, which will now be described in detail. The lesion is then removed by cutting away the tissue leading to the lesion and then removing the lesion.

Referring initially to FIGS. 23-25, stabilizing tube 196 is formed as an elongated hollow tube having an open distal end and a substantially frustoconical open proximal end portion, preferably formed of a series of resilient tapered arcuate segments 198. Inner diameter 199 of stabilizing tube 196 is preferably slightly larger than the outer diameter of ferrule 126 to facilitate the insertion of stabilizing tube 196 over ferrule 126.

Specifically, once tissue marker 128 is properly positioned, the user can then stabilize the location of marker 128 by inserting the proximal segment 144 of cable 124 through the open distal end of stabilizing tube 196 and sliding stabilizing tube 196 over cable 124 such that the open end thereof passes completely past ferrule 126. This causes segments 198 to cam radially outwardly as shown in FIG. 26.

Referring to FIG. 27, once the proximal end of stabilizing tube 196 passes distal of the distal end of ferrule 126, segments 198 are restored to their initial configuration thereby locking stabilizing tube 196 between ferrule 126 and abutment member 176. Tissue marker 128 is thus maintained perpendicular to abutment member 176 as shown in FIGS. 27-30 and cable 124 and is held in tension. Thereafter,

A further embodiment of a surgical apparatus for marking a particular location in body tissue constructed in accordance with the present disclosure will now be described with reference to FIGS. 31-37. Referring to FIGS. 31-33, tissue marker apparatus 200 includes a needle 210 having a sharpened distal end point 211 and a cable 224 secured to a proximal end of needle 210. Tip 211 is preferably conically shaped and extends beyond the diameter of body portion 213 of needle 210 forming an annular shoulder 215 (FIG. 36). A tissue marker 228 is slidably disposed over body portion 213 of needle 210 and is positioned in abutment with annular shoulder 215. An abutment member 276 is having a longitudinal throughbore is slidably disposed over body portion 213 of needle 210, adjacent the proximal end of tissue marker 228. The aforementioned assembly of components is passed through an advancing tube 250 which is securely mounted, e.g., by friction fit in the distal portion of a stepped throughbore formed in a housing 248. Housing 248 is provided with transversely extending projections 252 at a proximal end thereof and proximally extending threaded portion 256. A marker deployment actuator 260 having a longitudinal throughbore formed therein with threads formed along the inner surface near the distal end of the longitudinal throughbore is threadably mounted on threaded portion 256 of body 248. End cap 271 is provided having a longitudinal throughbore formed therein to receive cable 224 therethrough. A set screw 268 is also provided and is threadably received in a transverse threaded bore formed through the sidewall of cap 271 to clamp cable 224 to cap 271 so as to maintain connection of needle 210 and tissue marker 228 to tissue marker apparatus 200.

Tissue marker 228 preferably has a series of longitudinal slats 273 which may be formed as bisected segments connected by a reduced cross-sectional dimension portion, commonly referred to as a "living hinge" 275, to facilitate expansion of slats 273 upon deployment of tissue marker 228.

In use, as shown in FIGS. 36 and 37, tissue marking apparatus 200 is inserted in the patient's breast in a manner similar to that for tissue marker apparatus 100 in the previously described embodiment. Once tissue marker 228 is positioned adjacent the suspect lesion, marker deployment actuator 260 is rotated, as indicated by arrow "G" in FIG. 36. This rotational motion causes marker deployment actuator 260 to move in a proximal direction, as indicated by arrow "H", due to the threading of marker deployment actuator 160 and body 248. With cable 224 held fixed relative to marker deployment actuator 260 by set screw 268, body portion 213 of needle 210 is also pulled proximally as indicated by arrow "H" shown in FIG. 36. Tissue marker 228 is thereby compressed causing slats 273 to expand radially outwardly thereby marking the suspect lesion location.

It will be understood that various modifications may be made to the embodiments disclosed herein. For example, the cable is preferably formed of an elongated wire segment, however numerous different types of cable may be utilized, such as multi-strand braided wire. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

Claims

1. A surgical apparatus for marking a particular location in body tissue, which comprises:

   a needle including a housing and an elongated tube having a sharp distal end, the housing and elongated tube forming an longitudinal passageway therethrough;

   an elongated cable configured and dimensioned to pass through the longitudinal passageway;

   an elongated tissue marker attached adjacent a distal end of the elongated cable such that the elongated marker is movable between a retracted orientation and a deployed orientation; and

an actuator assembly operatively associated with the elongated marker, wherein movement of the actuator assembly from a first position to a second position moves the elongated marker from the retracted position to the deployed position.

2. A surgical apparatus for marking a particular location in body tissue according to claim 1, wherein when the elongated marker is in the retracted position a longitudinal axis of the elongated marker is substantially parallel to a longitudinal axis of the elongated cable.

3. A surgical apparatus for marking a particular location in body tissue according to claim 1, wherein when the elongated marker is in the deployed position a longitudinal axis of the elongated clip is substantially perpendicular to a longitudinal axis of the elongated cable.

4. A surgical apparatus for marking a particular location in body tissue according to claim 1, wherein the elongated marker is collapsible from the retracted position, wherein the elongated marker forms a substantially uniform transverse dimension with an outer surface of the elongated needle tube to the deployed position wherein the elongated marker has a transverse dimension which is substantially greater than that of the outer surface of the elongated needle tube.

5. A surgical apparatus for marking a particular location in body tissue according to claim 1, wherein the actuator assembly includes a first deployment actuator operatively connected to the housing and a second deployment actuator operatively associated with the first deployment actuator.

6. A surgical apparatus for marking a particular location in body tissue according to claim 5, wherein the actuator assembly further includes an advancing tube disposed between the first deployment actuator and the elongated marker.

7. A surgical apparatus for marking a particular location in body tissue according to claim 5, wherein the first deployment actuator is slidable with respect to the housing.

8. A surgical apparatus for marking a particular location in body tissue according to claim 5, wherein distal movement of the first deployment actuator moves the elongated marker from the retracted position to a longitudinally deployed position a predetermined distance away from a distal end of the sharp distal end of the elongated tube.

9. A surgical apparatus for marking a particular location in body tissue according to claim 5, wherein movement of the second deployment actuator from a first position to a second position rotates the elongated marker from a first orientation to a second orientation.

10. A surgical apparatus for marking a particular location in body tissue, which comprises:

a needle defining a longitudinal passageway therethrough;

an elongated cable configured and dimensioned to pass through the longitudinal passageway;

an elongated marker attached adjacent a distal end of the elongated cable such that the elongated marker is movable between a retracted orientation and a deployed orientation; and

a stabilizer member which is moved from a first position relative to the elongated cable and the elongated marker, to a second position in operative association with the elongated cable and the elongated clip to maintain the elongated marker in the deployed orientation.

11. A surgical apparatus for marking a particular location in body tissue according to claim 10, which further comprises a stop member disposed on the elongated cable at a point proximal of the elongated marker, wherein the stabilizer member is disposed between the elongated marker and the stop member such that the elongated cable is held in tension between the stop member and the elongated marker.

12. A surgical apparatus for marking a particular location in body tissue according to claim 11, wherein the stop member is a ferrule which is attached to the elongated cable member.

13. A surgical apparatus for marking a particular location in body tissue according to claim 10, which further comprises a clamp operatively associated with the elongated cable to selectively prevent longitudinal movement of the elongated cable relative to the needle.

14. A surgical apparatus for marking a particular location in body tissue according to claim 13, wherein the clamp includes a screw movable from a first position which permits longitudinal movement of the elongated cable relative to the apparatus housing, to a second position which prevents longitudinal movement of the elongated cable relative to the apparatus housing.

15. A surgical apparatus for marking a particular location in body tissue, which comprises:

a housing defining a longitudinal passageway therethrough;

an elongated cable configured and dimensioned to pass through the longitudinal passageway;

a tissue marker operatively connected to a distal end of the elongated cable, such that movement of the elongated cable from a first position to a second position moves the marker from a retracted orientation to a deployed orientation; and

a clamp operatively associated with the elongated cable to selectively prevent longitudinal movement of the elongated cable relative to the apparatus housing.

16. A surgical apparatus for marking a particular location in body tissue, according to claim 15, wherein the clamp is connected to the apparatus housing.

17. A surgical apparatus for marking a particular location in body tissue, according to claim 16, wherein the clamp includes a body portion defining a passageway therethrough to receive the elongated cable and a bias member movable from a released position, wherein the elongated cable is permitted to move longitudinally relative to the body portion and a clamped position, wherein the elongated cable is prevented from moving longitudinally relative to the body portion.

18. A surgical apparatus for marking a particular location in body tissue, according to claim 17, wherein the bias member is a screw threadably positioned in a bore formed in the body portion.

19. A surgical apparatus for marking a particular location in body tissue, which comprises:

a needle assembly including a housing and an elongated tube having a sharp distal end, the housing and elongated tube forming an longitudinal passageway therethrough;

a marker assembly including an elongated cable configured and dimensioned to pass through the longitudinal passageway and an elongated tissue marker attached adjacent a distal end of the elongated cable such that the elongated marker is movable between a retracted orientation and a deployed orientation, wherein the elongated cable is sufficiently rigid to maintain the elongated tissue marker in each of said retracted and deployed orientations; and

an actuator assembly operatively associated with the elongated marker, wherein movement of the actuator assembly from a first position to a second position moves the elongated marker from the retracted position to the deployed position.

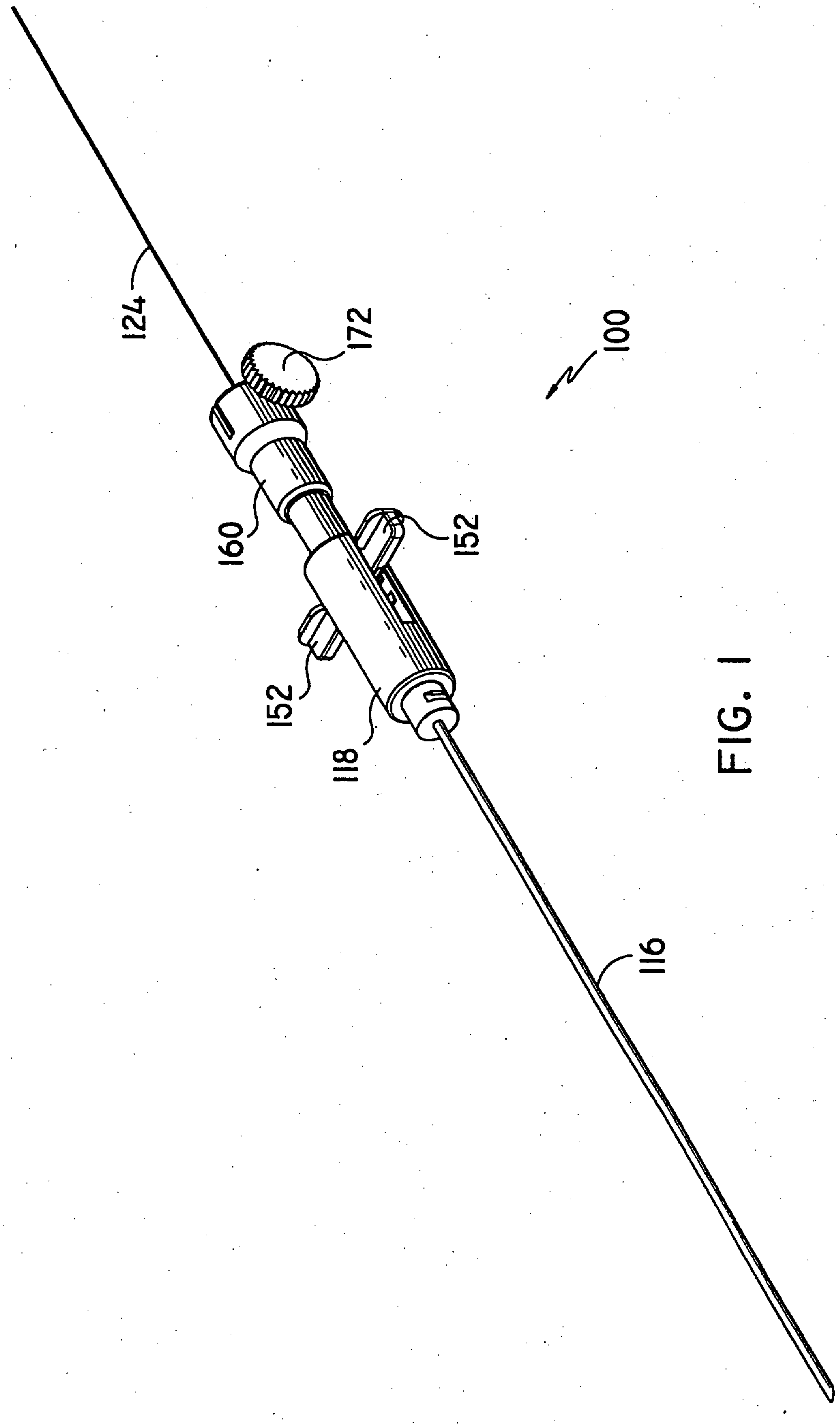

FIG. 1

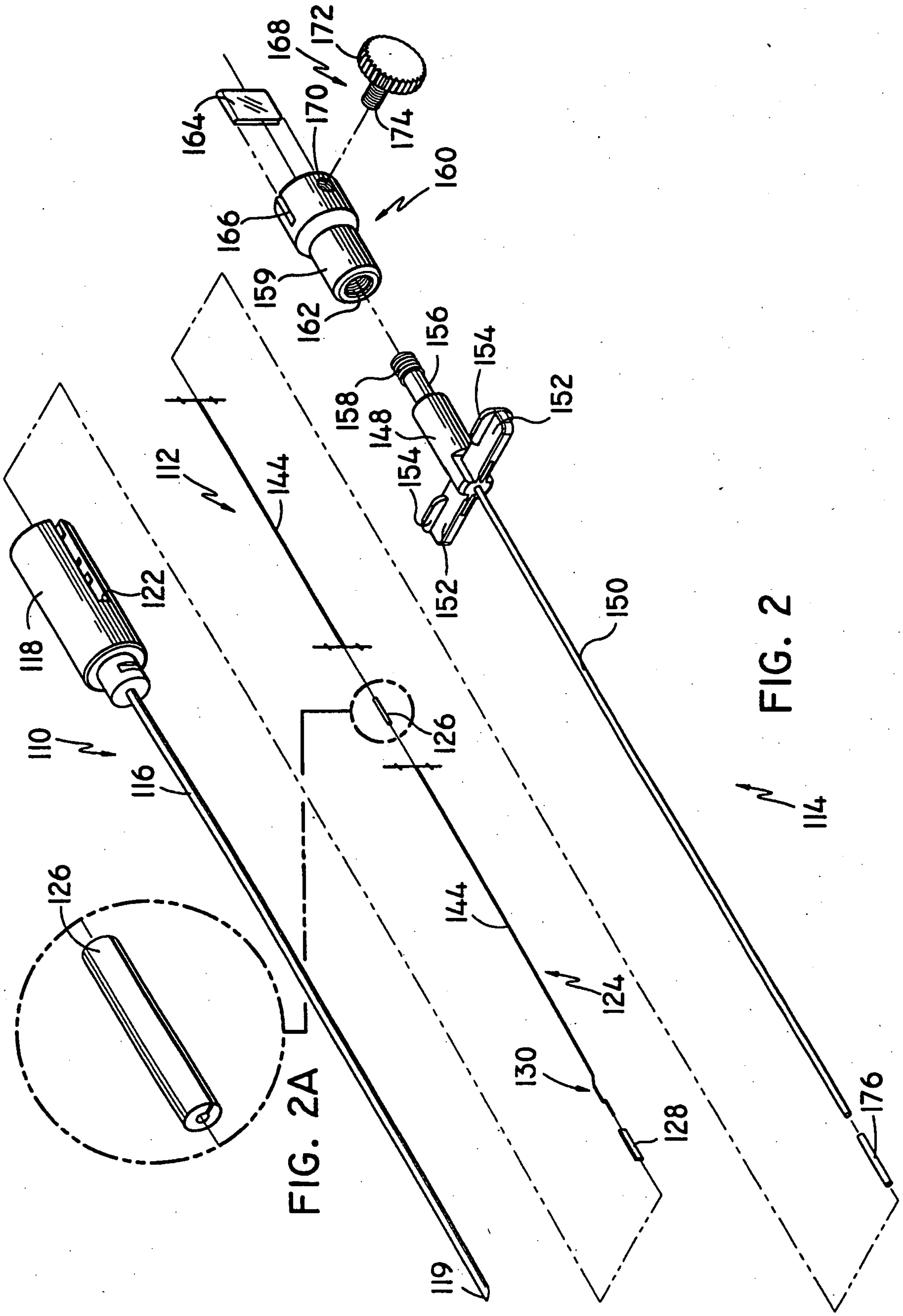
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FIG. 2

FIG. 2A

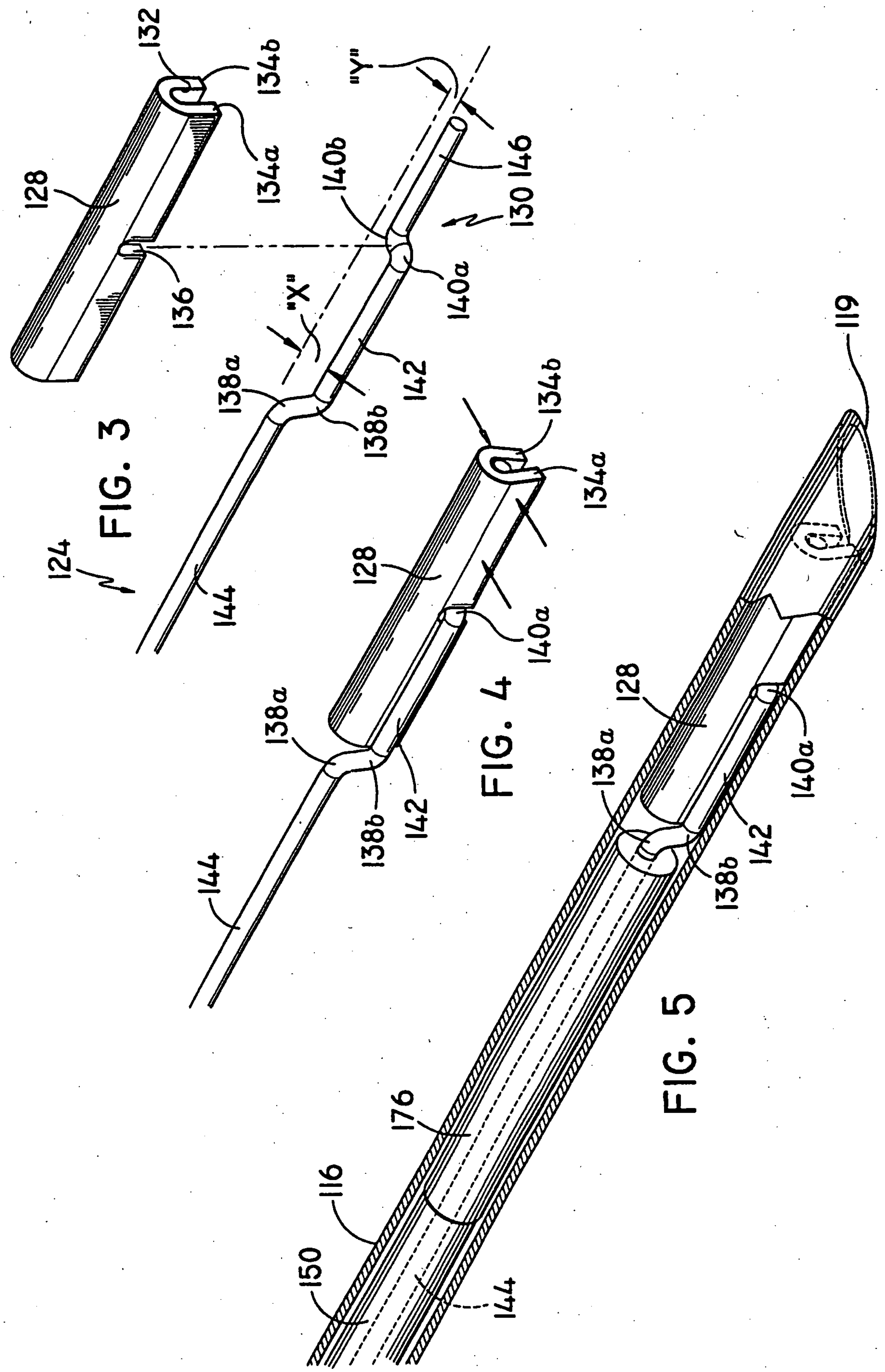

FIG. 3

FIG. 4

FIG. 5

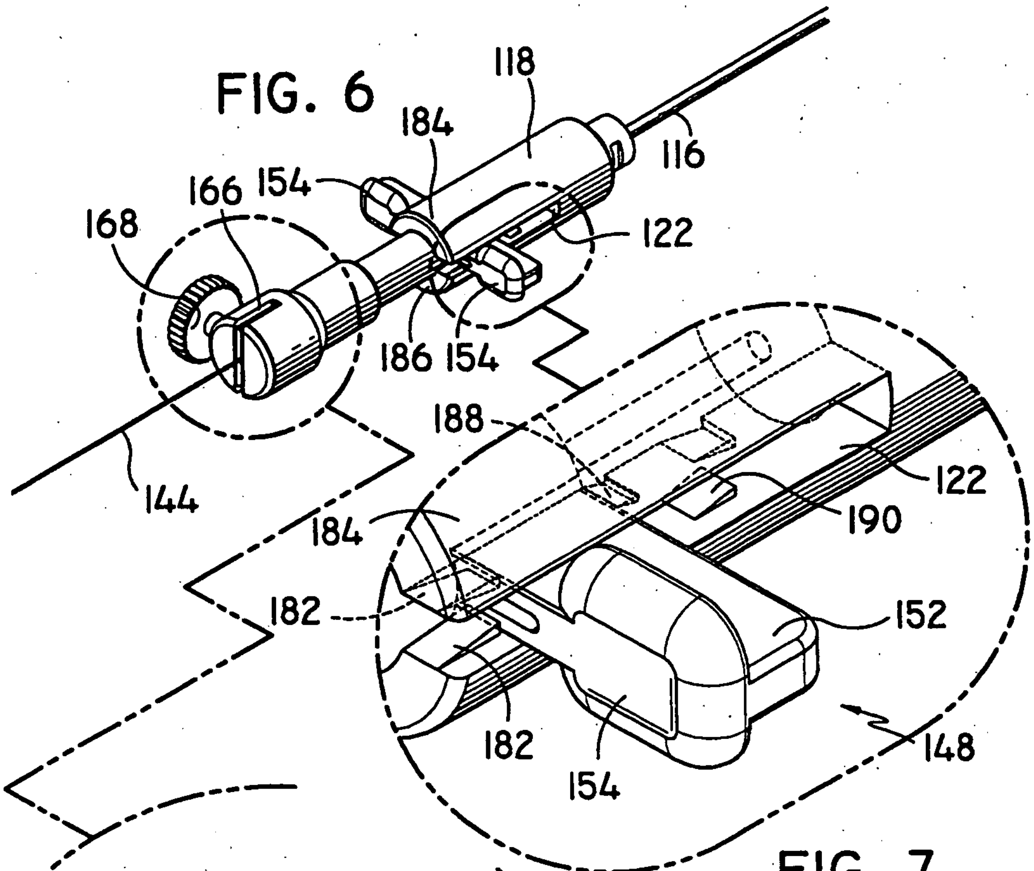

FIG. 6

FIG. 7

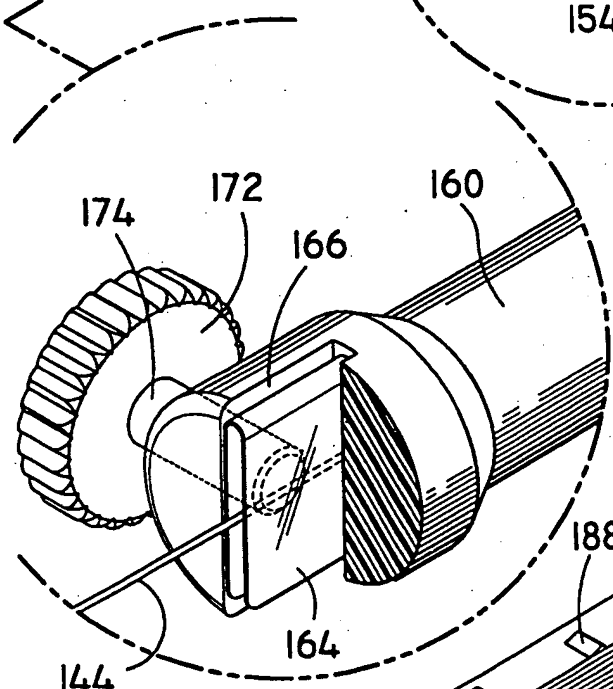

FIG. 9

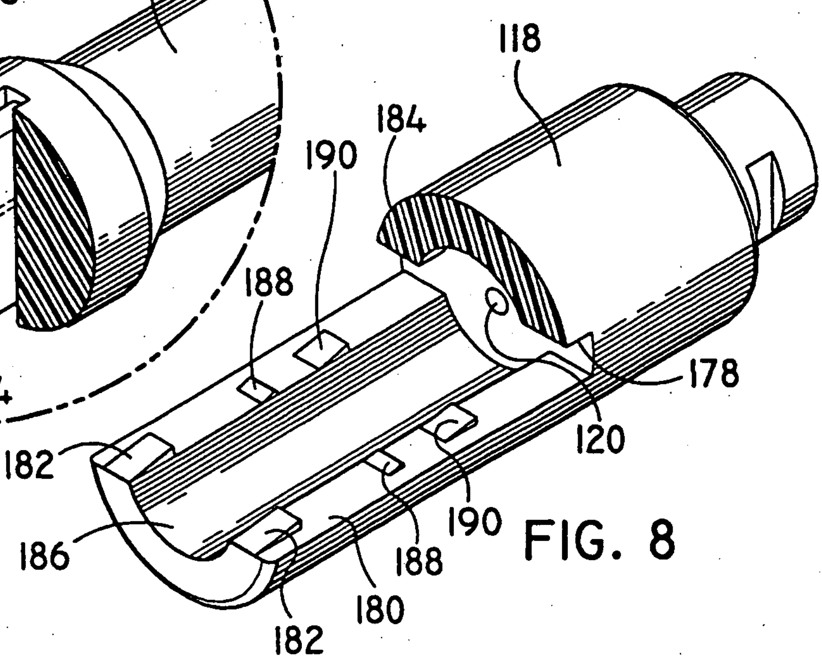

FIG. 8

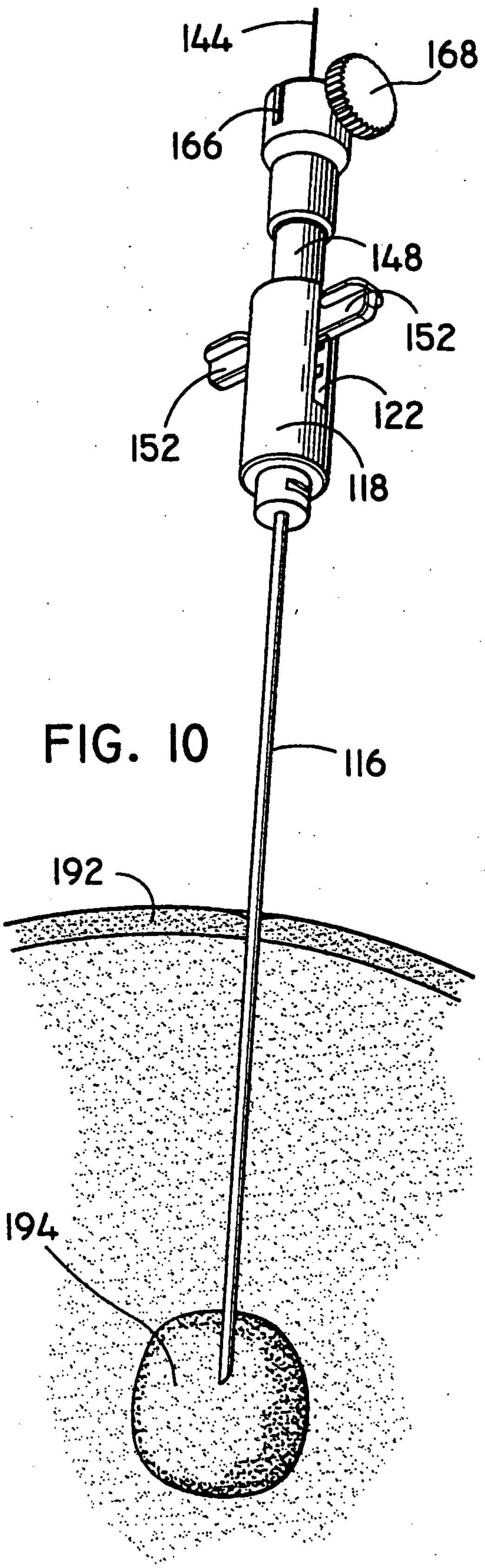
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FIG. 10

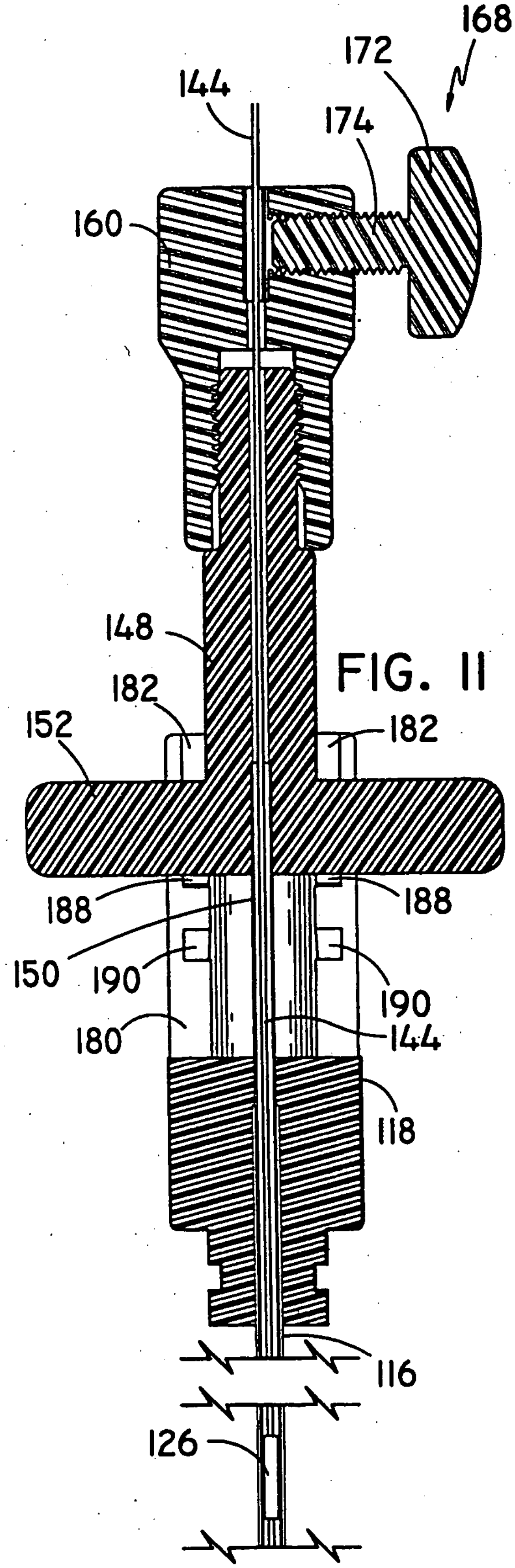
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FIG. 11

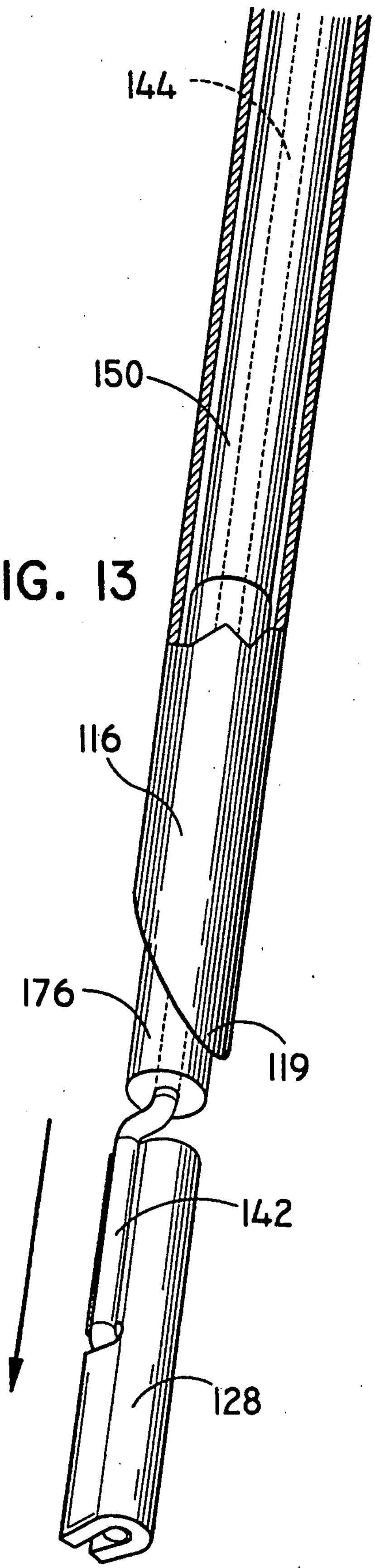
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FIG. 13

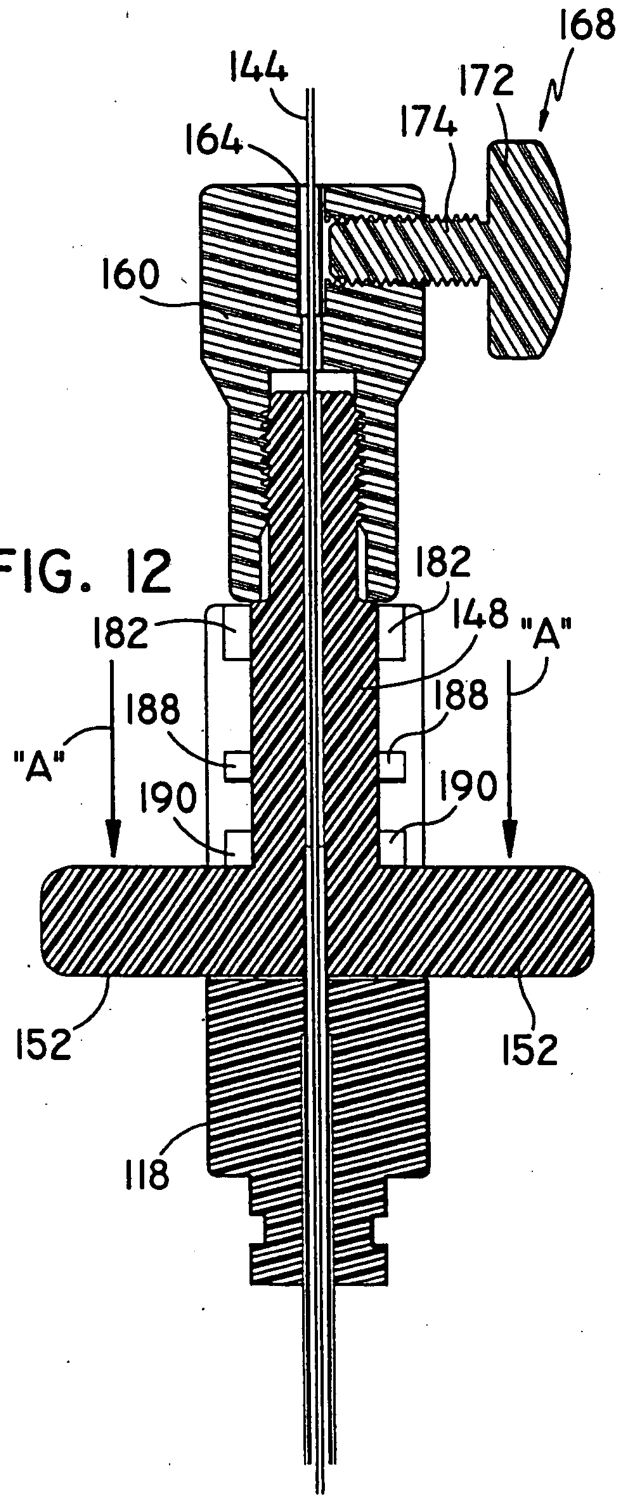
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FIG. 12

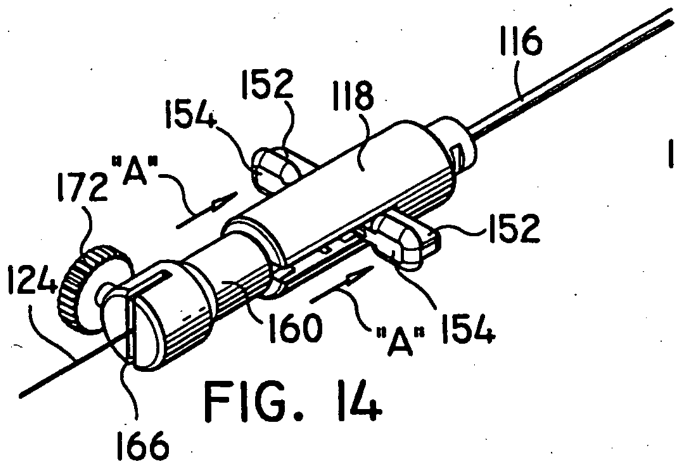

FIG. 14

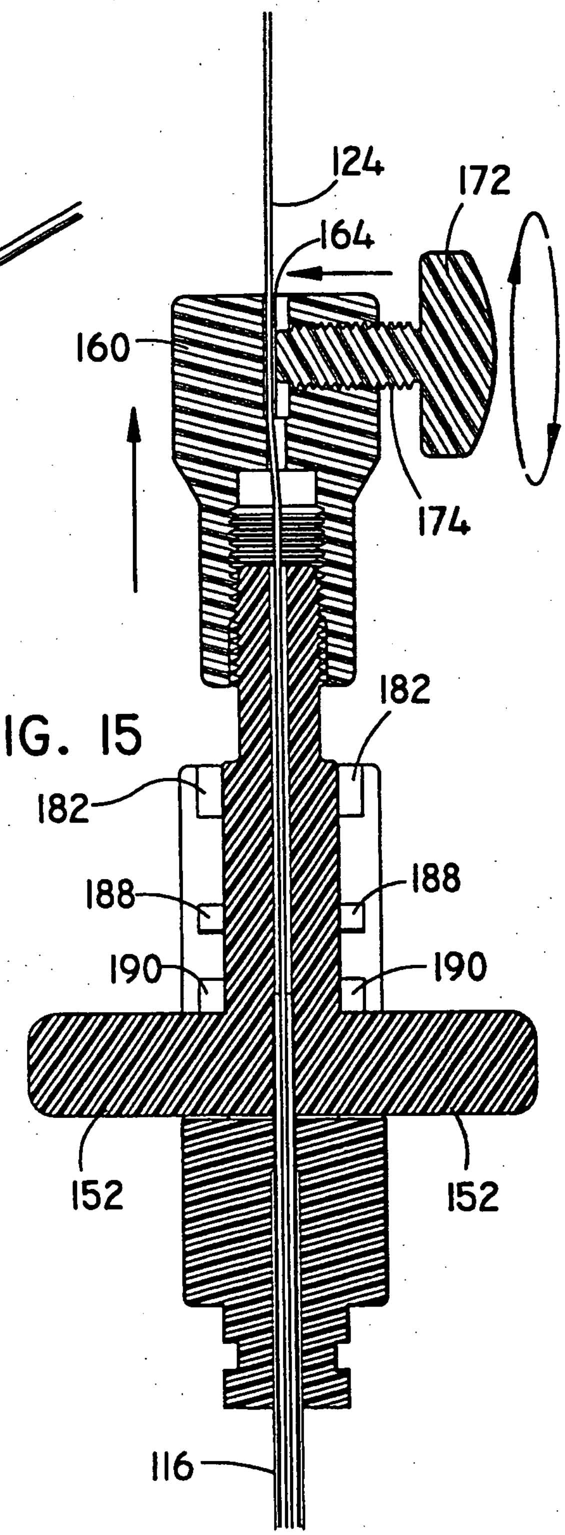

FIG. 15

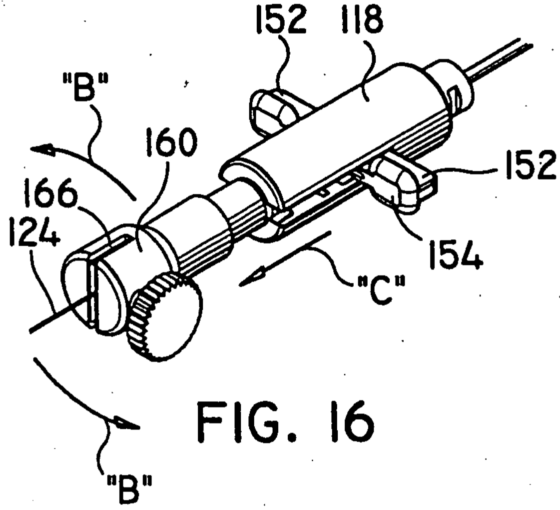

FIG. 16

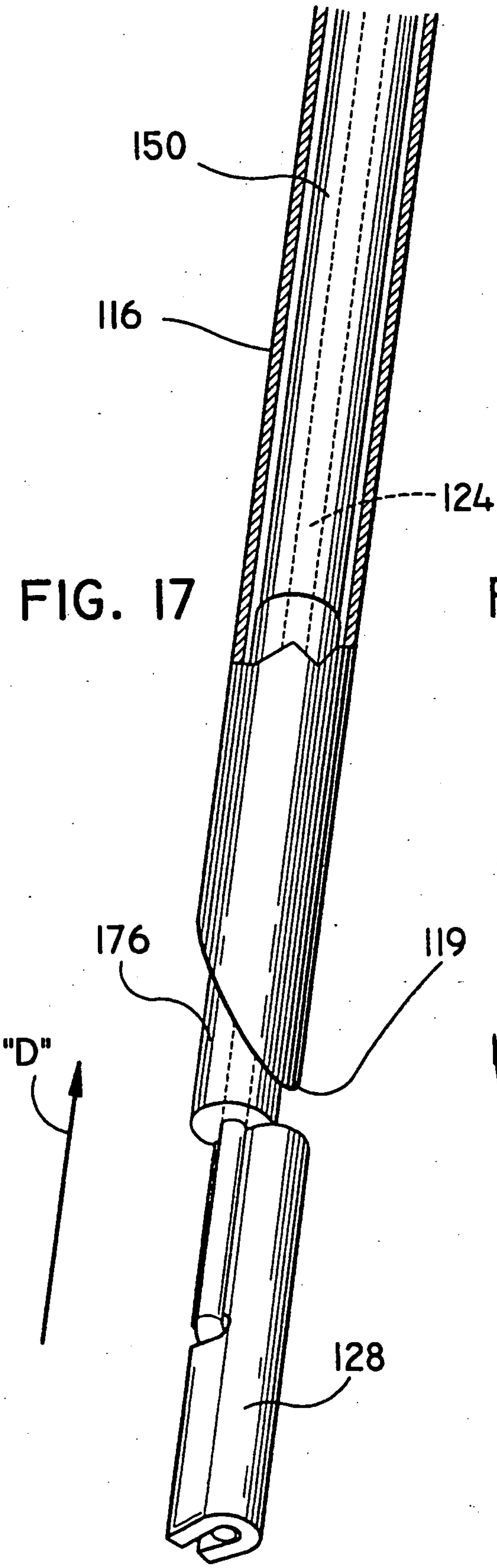

FIG. 17

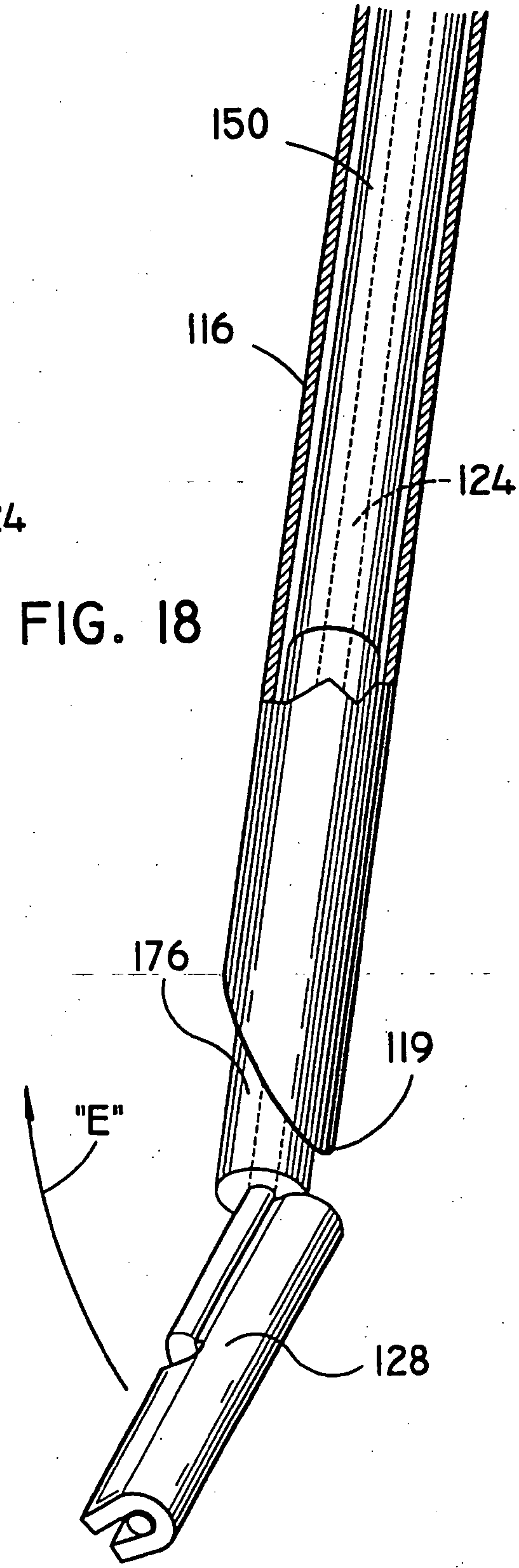

FIG. 18

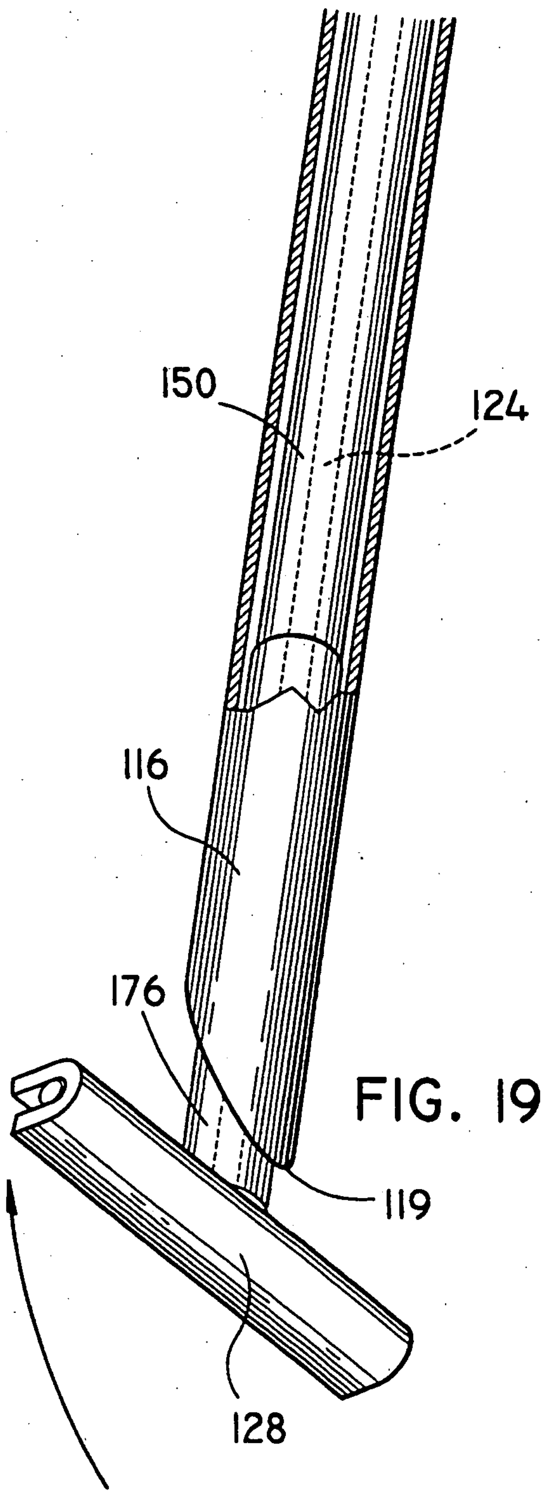

FIG. 19

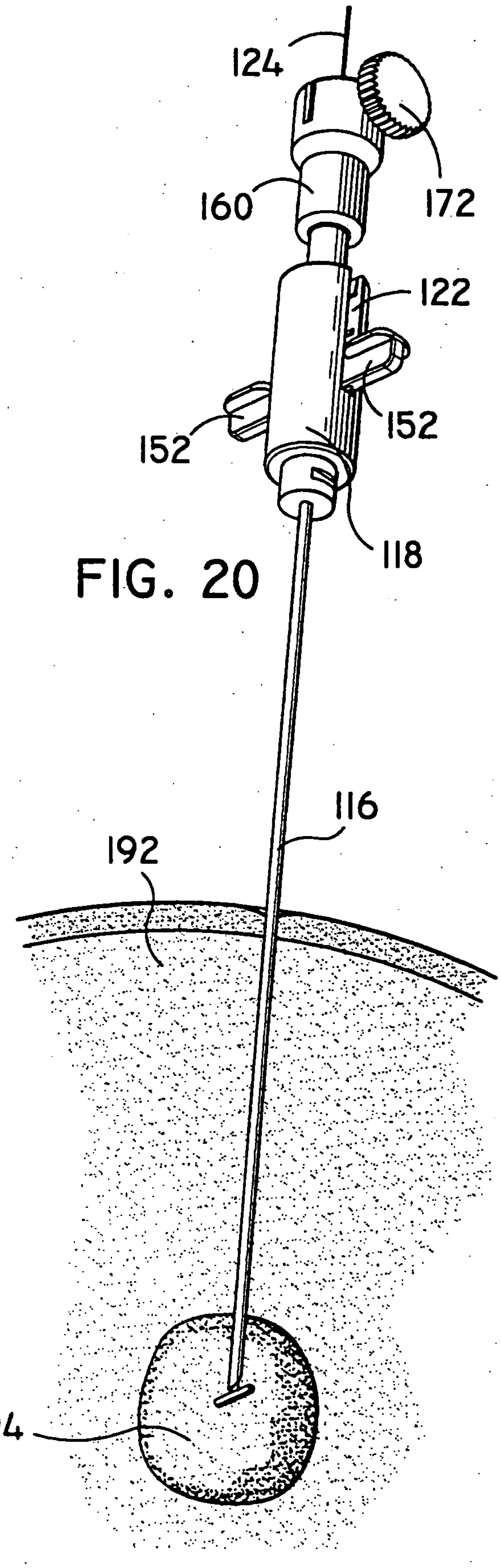

FIG. 20

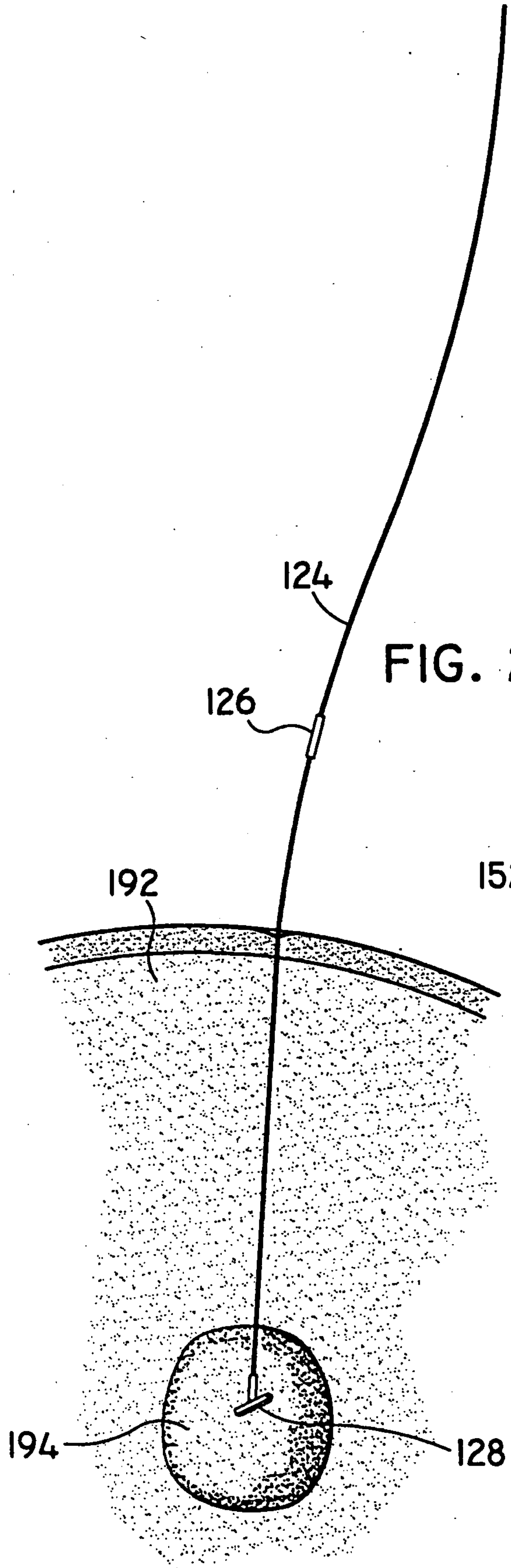
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FIG. 22

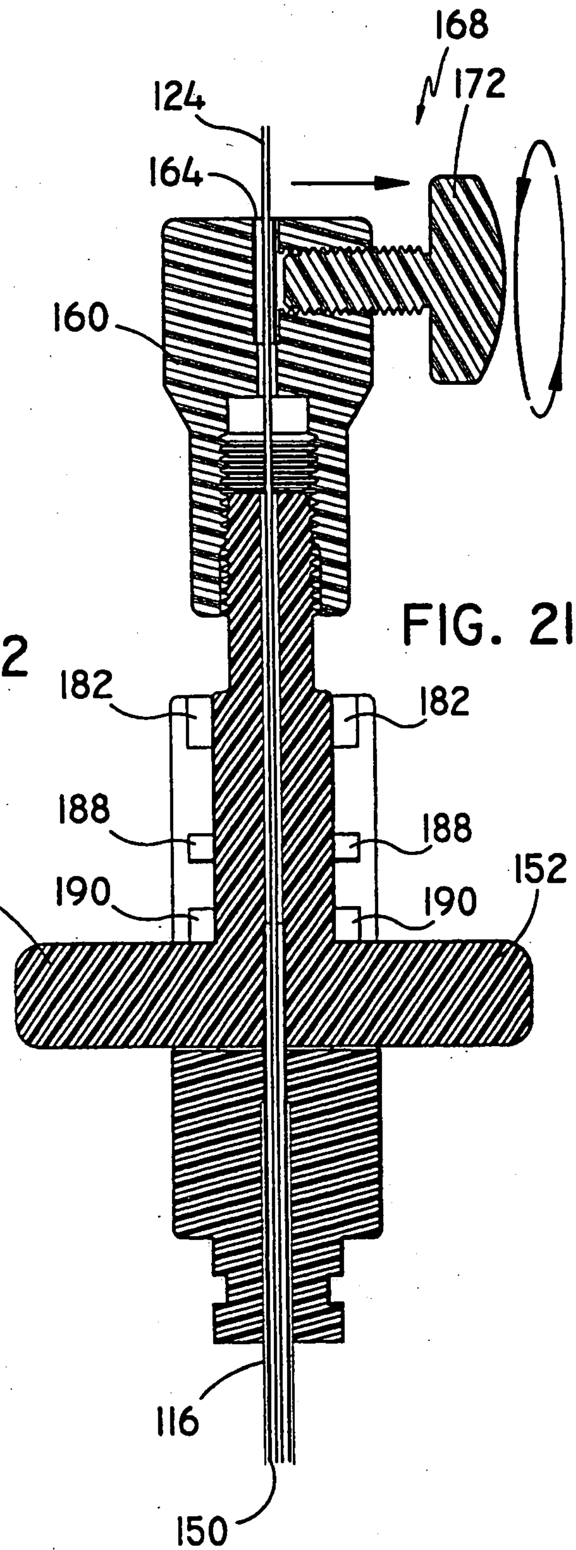
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FIG. 21

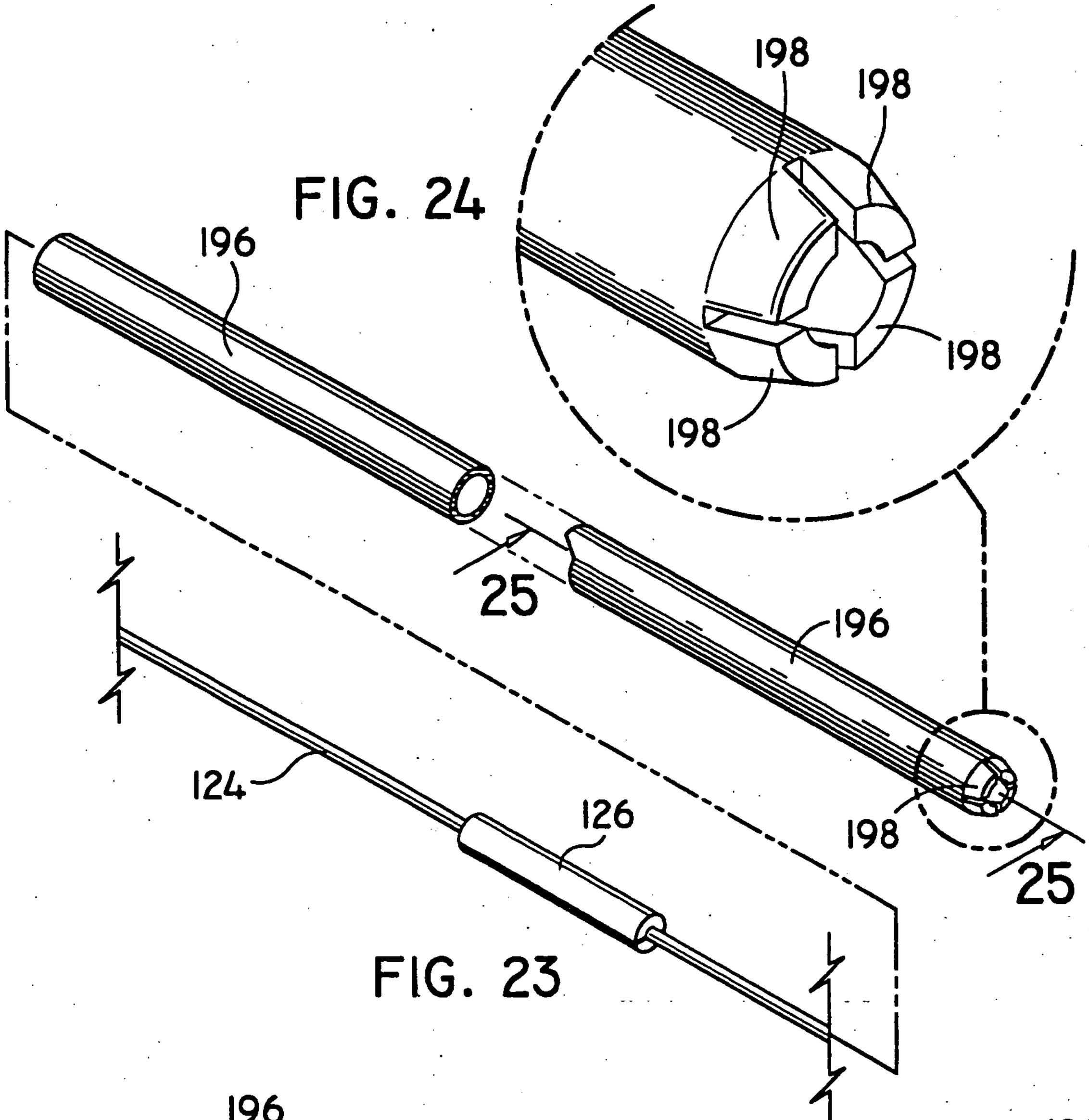


FIG. 24

FIG. 23

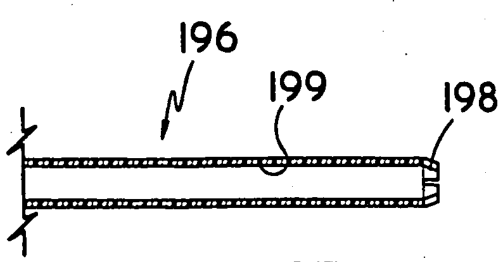


FIG. 25

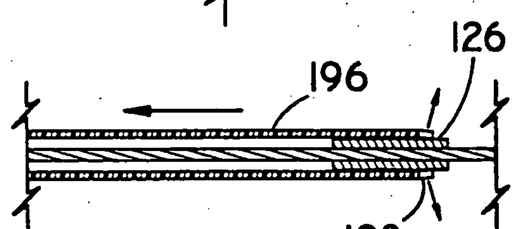
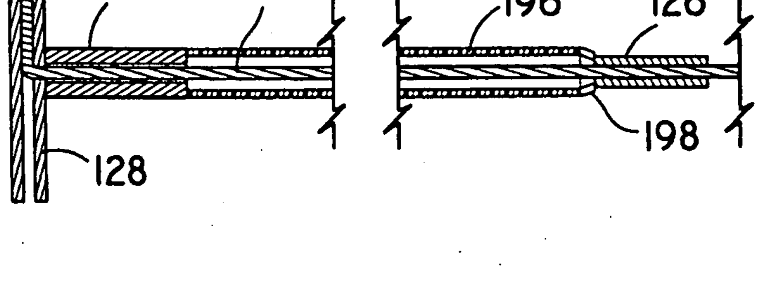


FIG. 26

FIG. 27



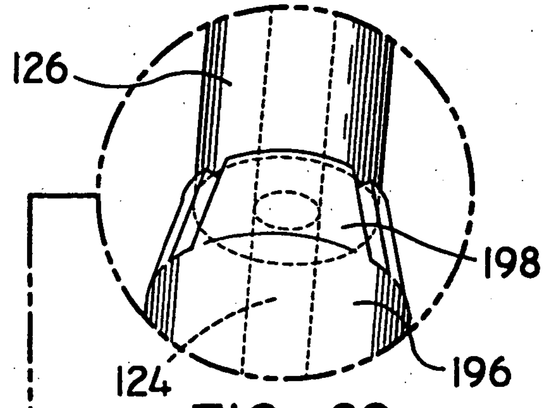


FIG. 29

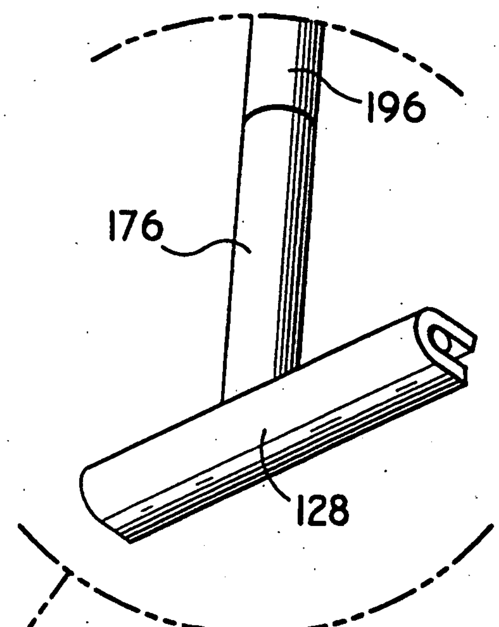


FIG. 30

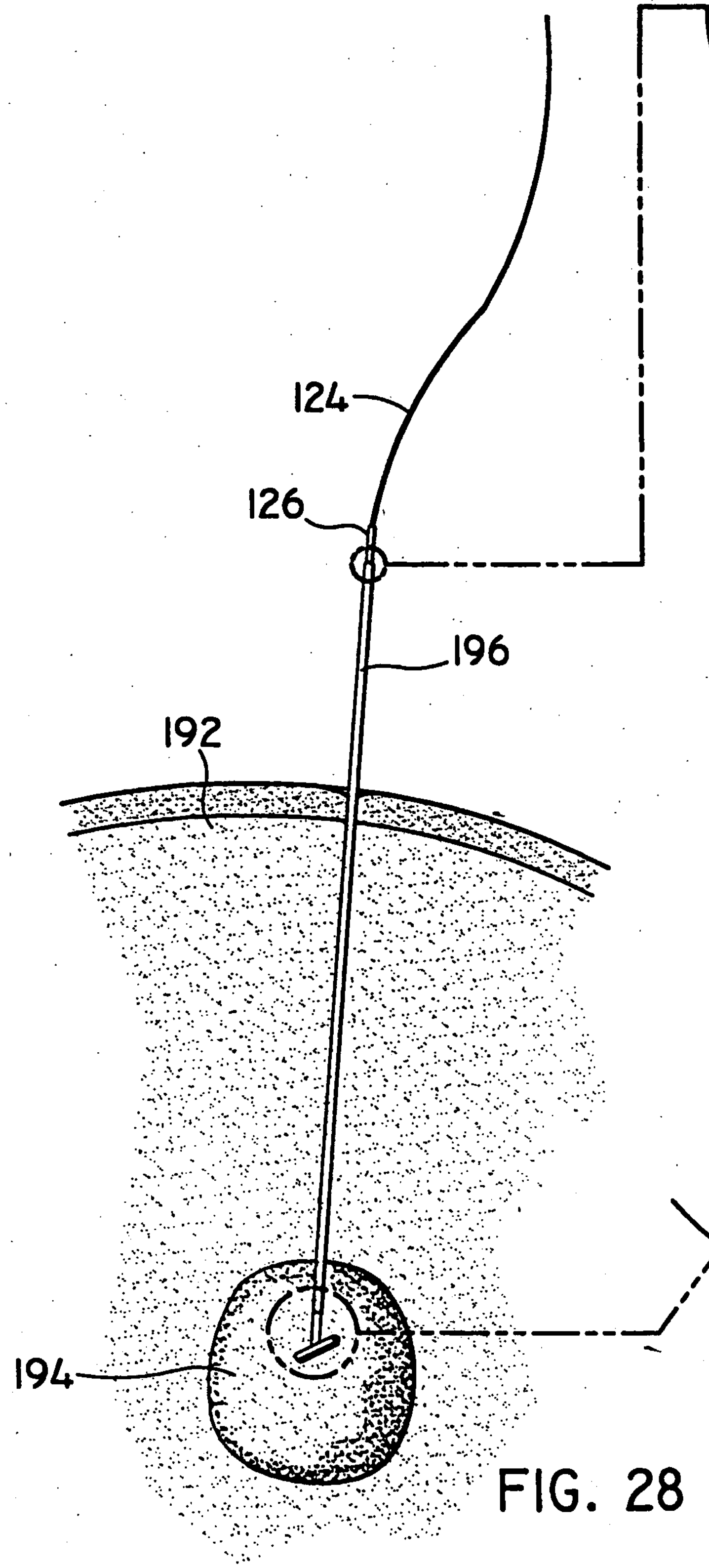


FIG. 28

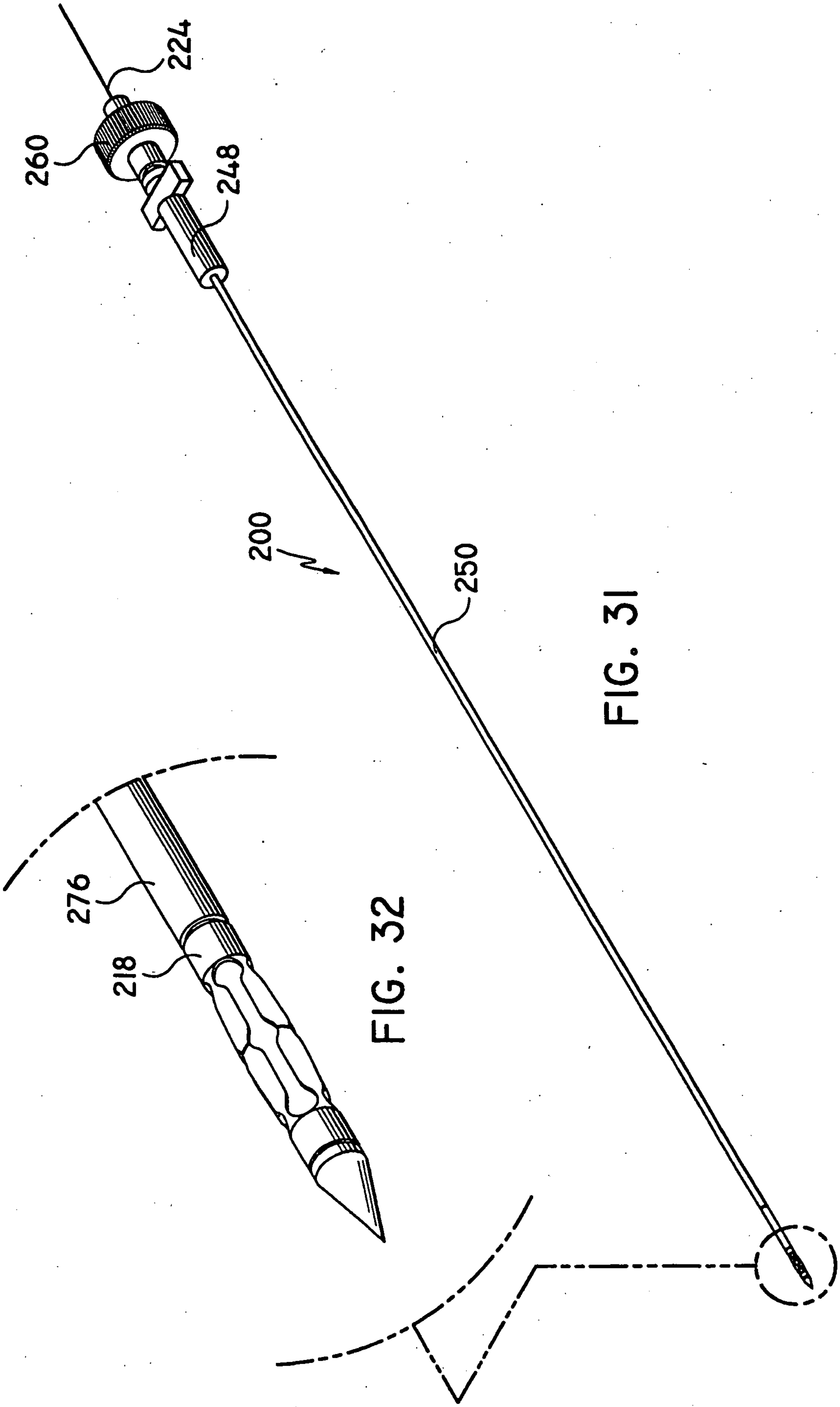


FIG. 31

FIG. 32

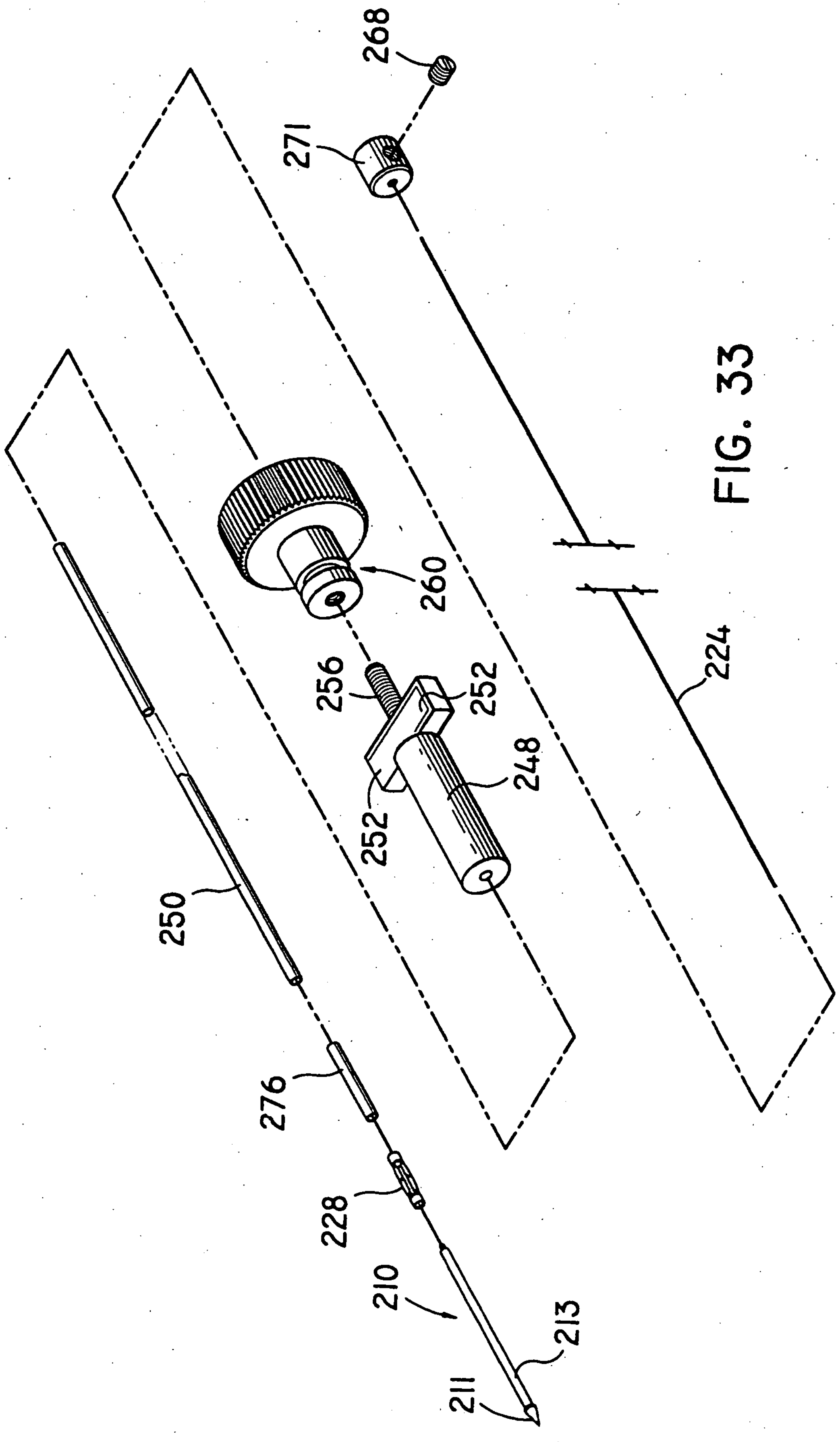


FIG. 33

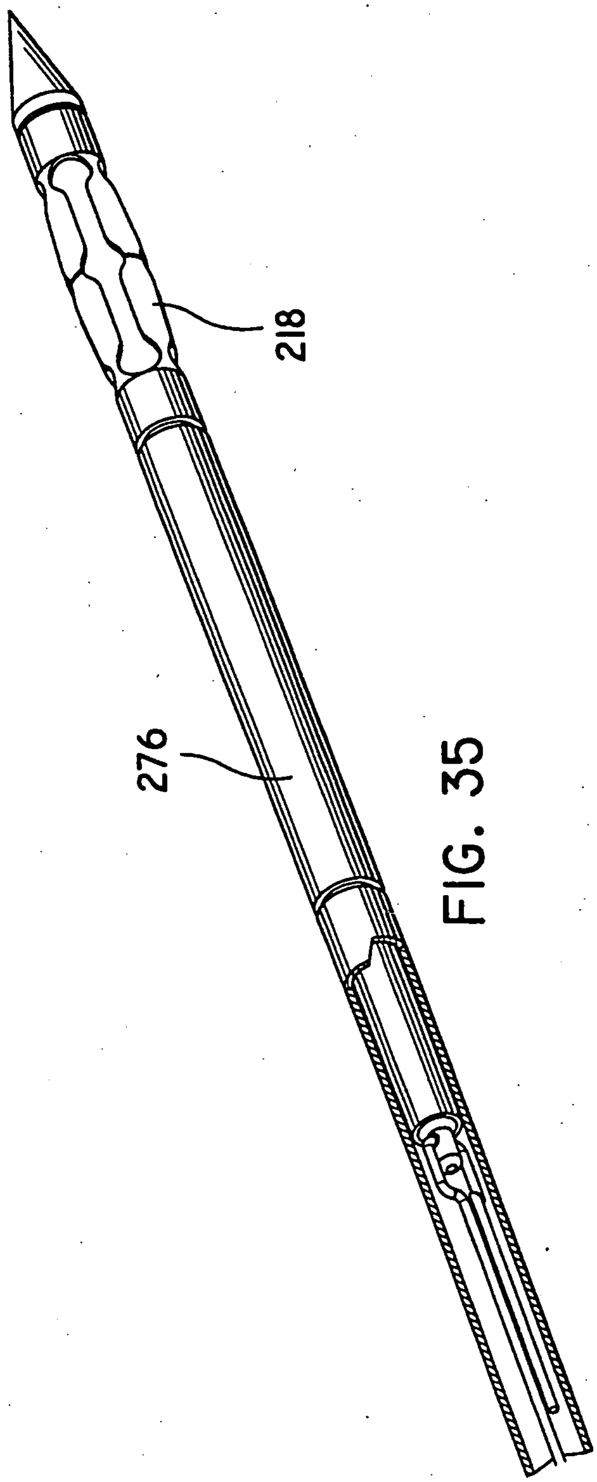


FIG. 35

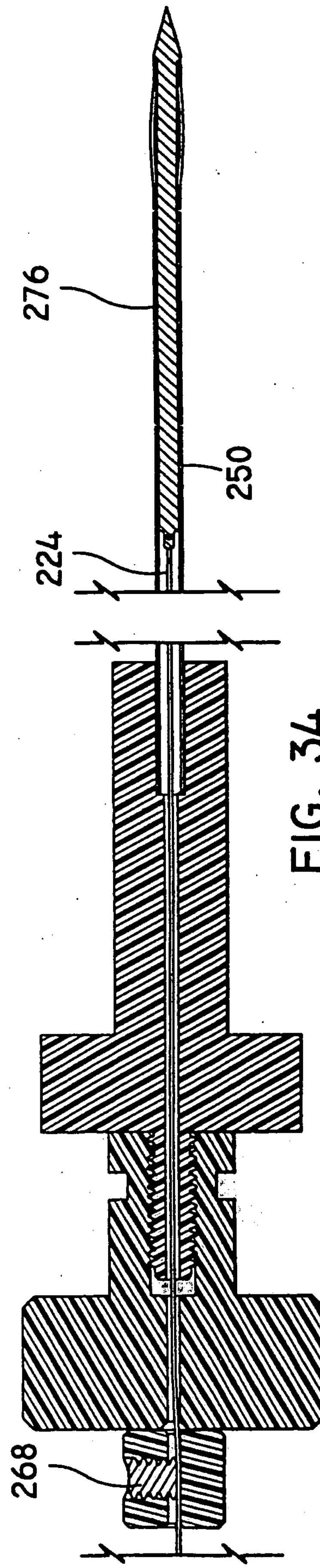


FIG. 34

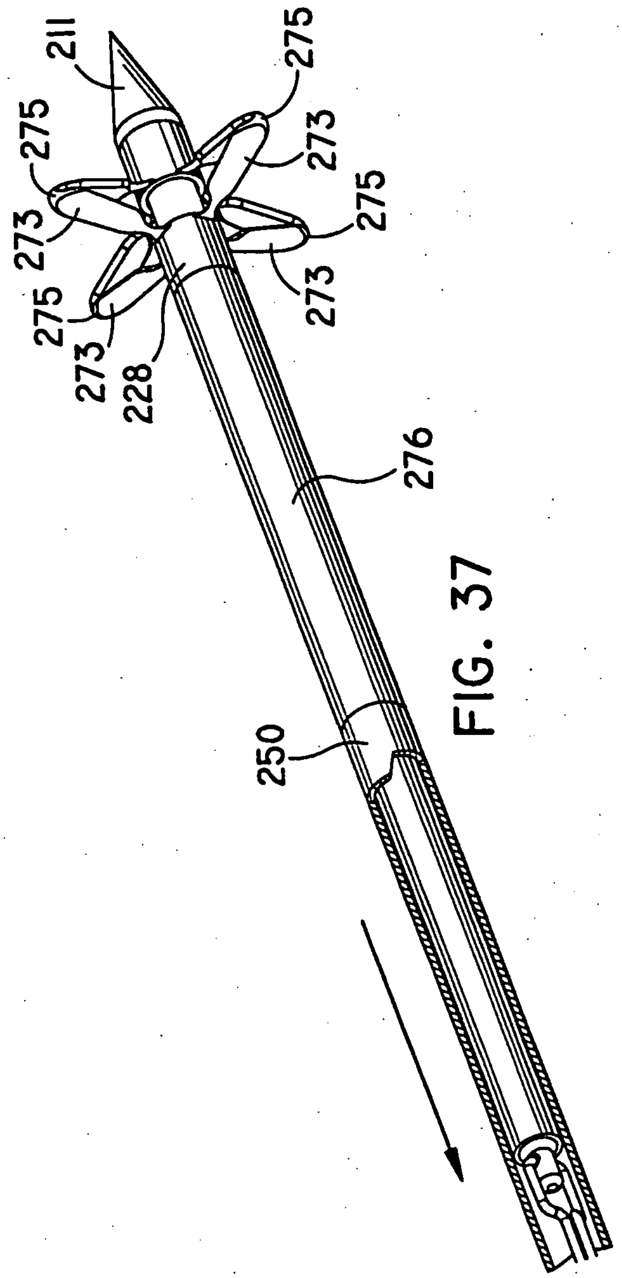

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FIG. 37

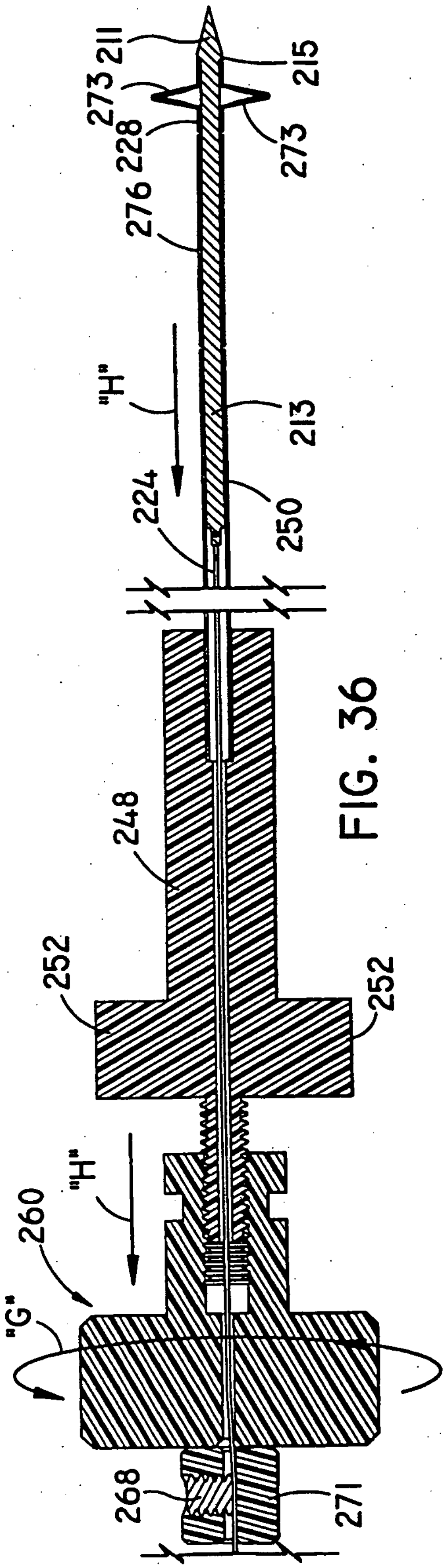
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FIG. 36